No. 06-179

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| Title: | Donna S. Riegel, Individually and as Administrator of the Estate of Charles R. Riegel, Petitioner<br>v.<br>Medtronic, Inc. |
| Docketed: | August 4, 2006 |
| Lower Ct: | United States Court of Appeals for the Second Circuit |
| Case Nos.: | (04-0412) |
| Decision Date: | May 16, 2006 |

Questions Presented

| ~~~Date~~~ | ~~~~~~~Proceedings and Orders~~~~~~~~~~~~~~~~~~~~~ |
|---|---|
| Aug 3 2006 | Petition for a writ of certiorari filed. (Response due September 5, 2006) |
| Aug 22 2006 | Order extending time to file response to petition to and including October 5, 2006. |
| Oct 5 2006 | Brief of respondent Medtronic, Inc. in opposition filed. |
| Oct 16 2006 | Reply of petitioners Charles R. Riegel and Donna S. Riegel filed. |
| Oct 18 2006 | DISTRIBUTED for Conference of November 3, 2006. |
| Nov 6 2006 | The Solicitor General is invited to file a brief in this case expressing the views of the United States. |
| May 23 2007 | Brief amicus curiae of United States filed. |
| Jun 4 2007 | Supplemental brief of petitioners Charles R. Riegel and Donna Riegel filed. (Distributed) |
| Jun 5 2007 | DISTRIBUTED for Conference of June 21, 2007. |
| Jun 25 2007 | Petition GRANTED. |
| Jul 5 2007 | The time to file the joint appendix and petitioners' brief on the merits is extended to and including August 27, 2007. |
| Aug 1 2007 | Motion for Suggestion of death and motion for substitution filed by petitioner Donna Riegel |
| Aug 1 2007 | Consent to the filing of amicus curiae briefs in support of either or neither party received from counsel for the petitioner. |
| Aug 7 2007 | Consent to the filing of amicus curiae briefs in support of either or neither party received from counsel for the respondent. |
| Aug 8 2007 | DISTRIBUTED for Conference of September 24, 2007 (CL 163). |
| Aug 10 2007 | Response to motion from respondent Medtronic, Inc. filed. (Distributed) |
| Aug 13 2007 | Reply of petitioners in support of motion filed. (Distributed) |
| Aug 27 2007 | Joint appendix filed. (Statement of costs received.) |
| Aug 27 2007 | Brief of petitioners Charles R. Riegel, et ux. filed. |
| Aug 27 2007 | Brief amici curiae of New York, et al. filed. |
| Aug 27 2007 | Brief amici curiae of Public Health Advocacy Institiute, et al. filed. |
| Aug 27 2007 | Brief amici curiae of Edward M.Kennedy, et al. filed. |
| Aug 27 2007 | Brief amicus curiae of Consumers Union of United States, Inc. filed. |
| Aug 27 2007 | Brief amicus curiae of American Association for Justice and Public Justice filed. |
| Aug 27 2007 | Brief amici curiae of AARP, et al. filed. |
| Sep 5 2007 | The time within which to file respondent's brief on the merits is extended to and including October 19, 2007. |

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|---|---|
| Oct 1 2007 | The motion of Donna Riegel, the administrator of the Estate of Charles R. Riegel, to be substituted in place of Charles R. Riegel, deceased, is GRANTED. The exercise of this Court's power to grant an untimely motion to substitute a party is not unprecedented. State Farm Mutual Auto. Ins. Co. v. Campbell, 537 U.S. 1042 (2002); see also Schact v. United States, 398 U.S. 58, 63-64 (1970) ("The procedural rules adopted by the Court for the orderly transaction of its business are not jurisdictional and can be relaxed by the Court in the exercise of its discretion.."); Stern & Gressman, Supreme Court Practice 350 (8th ed. 2002). The Chief Justice and Justice Scalia would deny the motion, because it was filed more than six months after the petitioner's death. See Supreme Court Rule 35.1 ("If the substitution of a representative of the deceased is not made within six months after the death of the party, the case shall abate" (emphasis added)). The fact that Rule 35.1 is not jurisdictional is not a reason to ignore it, particularly since here, unlike in Campbell, supra, the motion was opposed by the respondent. |
| Oct 15 2007 | SET FOR ARUMENT Tuesday, December 4, 2007. |
| Oct 19 2007 | Brief of respondent Medtronic, Inc. filed. |
| Oct 19 2007 | Brief amicus curiae of Chamber of Commerce of the United States of America filed. |
| Oct 19 2007 | Brief amicus curiae of United States filed. |
| Oct 19 2007 | Brief amici curiae of CropLife America, et al. filed. |
| Oct 19 2007 | Brief amicus curiae of Washington Legal Foundation filed. |
| Oct 19 2007 | Brief amicus curiae of Product Liability Advisory Council, Inc. filed. |
| Oct 19 2007 | Brief amici curiae of Advanced Medical Technology Association, et al. filed. |
| Oct 26 2007 | Motion of New York, et al. for leave to participate in oral argument as amici curiae and for divided argument filed. |
| Oct 30 2007 | CIRCULATED. |
| Nov 2 2007 | Motion of the Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument filed. |
| Nov 6 2007 | Opposition to motion of New York, et al. filed by petitioner. |
| Nov 9 2007 | Motion of New York, et al. for leave to participate in oral argument as amici curiae and for divided argument DENIED. |
| Nov 9 2007 | Motion of the Solicitor General for leave to participate in oral argument as amicus curiae and for divided argument GRANTED. |
| Nov 15 2007 | Reply of petitioner Donna S. Riegel individually, and as administrator of the estate of Charles R. Riegel filed. (Distributed) |
| Dec 4 2007 | Argued. For petitioner: Allison M. Zieve, Washington, D.C. For respondent: Theodore B. Olson, Washington, D.C.; and Edwin S. Kneedler, Deputy Solicitor General, Department of Justice, Washington, D.C. (for United States, as amicus curiae.) |
| Jan 16 2008 | Letter received from the Solicitor General. (Distributed) |

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No. 06-

In The
# Supreme Court of the United States

CHARLES R. RIEGEL and DONNA S. RIEGEL,
*Petitioners,*

v.

MEDTRONIC, INC.,
*Respondent.*

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Second Circuit

## PETITION FOR A WRIT OF CERTIORARI

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August 2006

## QUESTION PRESENTED

Whether the express preemption provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), preempts state-law claims seeking damages for injuries caused by medical devices that received premarket approval from the Food and Drug Administration.

## TABLE OF CONTENTS

QUESTION PRESENTED ..... i

TABLE OF AUTHORITIES ..... iv

INTRODUCTION ..... 1

OPINIONS BELOW ..... 3

JURISDICTION ..... 3

STATUTES AND REGULATIONS INVOLVED ..... 4

STATEMENT OF THE CASE ..... 5

A. The Medical Device Amendments ..... 6

B. The Decision in *Medtronic v. Lohr* ..... 9

C. Factual Background and Proceedings Below .. 11

REASONS FOR GRANTING THE WRIT ..... 14

A. The Federal And State Appellate Courts Are Deeply Divided Regarding The Application Of *Medtronic v. Lohr* To The Question Presented. ... 14

B. The Second Circuit's Holding Cannot Be Reconciled With *Lohr*. ..... 19

C. The Decision Below Leaves Patients Injured By The Most Risky Devices With No Remedy—A

Result Inconsistent With The History Of The MDA. ..... 22

CONCLUSION ..... 24

APPENDIX

Court of appeals' decision ..... 1a

District court's decision dated March 14, 2002 ..... 55a

District court's decision dated December 2, 2003 ..... 75a

## TABLE OF AUTHORITIES

CASES Pages

*Agostini v. Felton*,
521 U.S. 203 (1997) ..... 21

*Alexander v. Sandoval*,
532 U.S. 275 (2001) ..... 21

*American Airlines, Inc. v. Wolens*,
513 U.S. 219 (1995) ..... 21

*Armstrong v. Optical Radiation Corp.*,
57 Cal. Rptr. 2d 763 (Cal. App. 1996),
*review denied*, 1997 Cal. LEXIS 833
(Feb. 19, 1997) ..... 18

*Baird v. American Medical Optics*,
693 A.2d 904 (N.J. Super., App. Div.),
*modified and remanded*,
713 A.2d 1019 (N.J. 1997) ..... 17

*Bates v. DowAgroSciences*,
125 S. Ct. 1788 (2005) ..... 13, 18, 23

*Brooks v. Howmedica*,
535 U.S. 1056 (2002) ..... 2, 14

*Cipollone v. Liggett Group*,
505 U.S. 504 (1992) ..... 13, 18

*Connelly v. Iolab Corp.*,
927 S.W.2d 848 (Mo. 1996),
*cert. dismissed*, 520 U.S. 1260 (1997) ..... 16

*English v. General Electric Co.*,
496 U.S. 72 (1990) ..... 22

*Fry v. Allergan Medical Optics*,
695 A.2d 511 (R.I.),
*cert. denied*, 522 U.S. 952 (1997) ..... 16, 17

*Geier v. American Honda Motor Co.*,
529 U.S. 861 (2000) ..... 18

*Goodlin v. Medtronic, Inc.*,
167 F.3d 1367 (11th Cir. 1999) ..... 2, 3, 15, 19, 23

*Goodyear Atomic Corp. v. Miller*,
486 U.S. 174 (1988) ..... 13

*Green v. Dolsky*,
685 A.2d 110 (Pa. 1996),
*cert. denied*, 520 U.S. 1168 (1997) ..... 16

*Haidak v. Collagen Corp.*,
67 F. Supp. 2d 21 (D. Mass. 1999) ..... 15

*Horn v. Thoratec*,
376 F.3d 163 (3d Cir. 2004) ..... 2, 14, 16, 17, 21

*Hutto v. Davis*,
454 U.S. 370 (1982) ..... 21

*Kemp v. Medtronic, Inc.*,
231 F.3d 216 (6th Cir. 2000),
*cert. denied*, 534 U.S. 818 (2001) ..... 2, 14

*Kernats v. Smith Industrial Medical System*,
669 N.E.2d 1300 (Ill. App.),
*appeal denied*, 675 N.E.2d 634 (Ill. 1996),
*cert. denied*, 522 U.S. 1044 (1998) ..... 1, 17

*Knisley v. Medtronic*,
126 S. Ct. 420 (2005) ..... 2

*Lakie v. SmithKline Beecham*,
965 F. Supp. 49 (D.D.C. 1997) ..... 15

*Martin v. Medtronic, Inc.*,
254 F.3d 573 (5th Cir. 2001),
*cert. denied*, 534 U.S. 1078 (2002) ..... 2, 16

*Martin v. Telectronics Pacing Systems, Inc.*,
105 F.3d 1090 (6th Cir. 1997),
*cert. denied*, 522 U.S. 1075 (1998) ..... 16

*Maryland v. Wilson*,
519 U.S. 408 (1997) ..... 21

*Mears v. Marshall*,
944 P.2d 984 (Ore. App. 1997),
*review denied*, 961 P.2d 217 (Ore. 1998) ..... 17

*Medtronic, Inc. v. Lohr*,
518 U.S. 470 (1996) ..... *passim*

*Mitchell v. Collagen Corp.*,
126 F.3d 902 (7th Cir. 1997),
*cert. denied*, 523 U.S. 1020 (1998) ..... 14, 17, 21

*Niehoff v. Surgidev*,
950 S.W.2d 816 (Ky. 1997),
*cert. denied*, 523 U.S. 1005 (1998) ..... 2, 3, 14, 16

*Oja v. Howmedica*,
111 F.3d 782 (10th Cir. 1997) ..... 3, 17, 22

*Papike v. Tambrands, Inc.*,
107 F.3d 737 (9th Cir. 1997) ..... 17

*Quillen v. American Hospital Supply Corp.*,
1997 U.S. Dist. LEXIS 6974
(N.D. Okla. Mar. 31, 1997) ..... 15

*Silkwood v. Kerr-McGee Corp.*,
464 U.S. 238 (1984) ..... 22

*Sowell v. Bausch & Lomb*,
656 N.Y.S.2d 16 (N.Y. App. Div. 1997) ..... 15

*Sprietsma v. Mercury Marine*,
537 U.S. 51 (2002) ..... 18, 22

*State ex rel Miller v. New Womyn, Inc.*,
679 N.W.2d 593 (Iowa 2004) ..... 14, 17

*Steele v. Collagen Corp.*,
63 Cal. Rptr. 2d 879 (Cal. App. 1997) ..... 16, 17

*Walker v. Johnson & Johnson Vision Products, Inc.*,
552 N.W.2d 679 (Mich. App. 1996) ..... 16, 17

*Weiland v. Telectronics Pacing System, Inc.*,
721 N.E.2d 1149 (Ill. 1999) ..... 3, 14, 15

*Worthy v. Collagen Corp.*,
967 S.W.2d 360 (Tex.),
*cert. denied*, 524 U.S. 954 (1998) ..... 16

*Wutzke v. Schwagler*,
940 P.2d 1386 (Wash. App. 1997),
*review denied*, 953 P.2d 96 (Wash. 1998) ..... 17

**STATUTORY MATERIALS**

21 U.S.C. § 360c(a) ..... 6

21 U.S.C. § 360c(a)(1)(A) ..... 6

21 U.S.C. § 360c(a)(1)(B) ..... 6

21 U.S.C. § 360c(a)(1)(C) ..... 6

21 U.S.C. § 360c(f)(1)(A) ..... 7

21 U.S.C. § 360e(b)(1)(A) ..... 7

21 U.S.C. § 360e(b)(1)(B) ..... 7

21 U.S.C. § 360j(g) ..... 16

21 U.S.C. § 360k ..... 4

21 U.S.C. § 360k(a) ..... *passim*

21 U.S.C. § 360k(b) ..... 8

28 U.S.C. § 1254(1) ..... 3

28 U.S.C. § 1257 ..... 1

P.L. No. 94-295, 90 Stat. 539 (1976) ..... 6

H.R. Rep. 853, 94th Cong., 2d Sess. (1976) ..... 6, 8

121 Cong. Rec. S1640 (Apr. 17, 1976) ..... 6

**REGULATIONS**

21 C.F.R. § 801.420 ..... 8, 20

21 C.F.R. § 801.430 ..... 15

21 C.F.R. § 801.430(c) ..... 6

21 C.F.R. § 801.430(d) ..... 6

21 C.F.R. § 801.430(e) ..... 6

21 C.F.R. § 801.430(f) ..... 8

21 C.F.R. § 808.1 ..... 8, 20

21 C.F.R. § 808.1(d) ..... 4, 8, 11, 15, 20

21 C.F.R. § 808.1(d)(1) ..... 8, 20

21 C.F.R. § 814.20 ..... 7

21 C.F.R. § 814.39(a) ..... 7

21 C.F.R. § 814.39(d) ..... 7

21 C.F.R. § 814.44 ..... 7

21 C.F.R. § 886.4392 ..... 8

## INTRODUCTION

Nine years ago, this Court considered a petition for certiorari that raised the same question presented here: whether state-law damages claims concerning medical devices that received premarket approval ("PMA") from the Food and Drug Administration ("FDA") are preempted by the 1976 Medical Device Amendments ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). *See Smith Industries Medical Systems, Inc. v. Kernats*, No. 96-1405, *cert. denied*, 522 U.S. 1044 (1998). Responding to the Court's request for advice on the petition, the Solicitor General agreed with the plaintiffs-respondents that PMA does not preempt state-law damages claims. *See* Brief of the United States As Amicus Curiae in *Kernats* at 14-18 (filed Dec. 1997). Although for reasons inapplicable here the Solicitor General recommended against granting certiorari in that case, he noted that "[t]he current division among the lower courts . . . would normally provide a strong justification for this Court to grant review and definitively resolve the conflict." *Id.* at 18.[1]

Today, the division among the lower courts, and thus the need for this Court's guidance, is even more pronounced than when the Solicitor General noted the conflict in his brief in *Kernats*. Today, an injured patient can maintain suit against the manufacturer of a PMA device in the courts of the Eleventh Circuit, for example, but not of the Second Circuit, and in Illinois state courts, for example, but not in Illinois federal

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[1]The Solicitor General argued that the petition should be denied because the Court did not have jurisdiction to review the state appellate court decision (which was not final under 28 U.S.C. § 1257), because the appellate court's holding that PMA did not preempt damages claims was correct, and because of the pendency of a proposed FDA interpretive rule (later withdrawn) regarding preemption.

courts. In fact, three circuit courts have reviewed the same FDA approval with respect to the same medical device, made by the same company, and reached two opposite conclusions. *Compare Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) (no preemption of state-law damages claims), *with Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000) (preemption), and *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001) (same). Because the courts' divergent analyses of the pre-emption question focus on the three opinions in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the conflict manifests not only a disagreement over the issue of PMA preemption, but also a disagreement about the obligation of lower courts to follow the holding of a majority opinion of this Court.

Adding to the confusion, the United States, in a letter brief filed in a Third Circuit case, *Horn v. Thoratec*, 376 F.3d 163 (3d Cir. 2004), reversed its position on preemption, making an argument that, by its own admission, contradicts the argument it made to this Court in *Kernats*. *See id.* at 177-78 (describing brief). The government's flip-flop heightens the already "strong justification for this Court to grant review and definitively resolve" the question presented.

In the past several years, this Court has denied review of petitions presenting substantially the same question presented here. *See, e.g., Knisley v. Medtronic*, 126 S. Ct. 420 (2005) (denying *cert.*); *Martin v. Medtronic*, 534 U.S. 1078 (2002) (same); *Brooks v. Howmedica*, 535 U.S. 1056 (2002) (same); *Kemp v. Medtronic*, 534 U.S. 818 (2001) (same); *Surgidev Corp. v Niehoff*, 523 U.S. 1005 (1998) (same). For the most part, opponents of review suggested that the courts that found no preemption might change their minds or be overturned en banc. That has not happened. The decisions finding no pre-emption—including the Eleventh Circuit's 1999 decision in

*Goodlin v. Medtronic* 167 F.2d 1367, the Tenth Circuit's 1997 decision in *Oja v. Howmedica*, 111 F.3d 782, the Illinois Supreme Court's 1999 decision in *Weiland v. Telectronics Pacing Systems*, 721 N.E.2d 1149, and the Kentucky Supreme Court's 1997 decision in *Niehoff v. Surgidev*, 950 S.W.2d 816—remain the law in those jurisdictions. Accordingly, it is now clear that the deep division among the lower courts is firmly established and will not be resolved without this Court's intervention.

## OPINIONS BELOW

The decision of the United States Court of Appeals for the Second Circuit is not yet reported in F.3d and is reproduced in the Appendix at 1a. The district court's March 14, 2003 decision granting Respondent's motion for summary judgment in part is unreported and is reproduced in the Appendix at 55a. The district court's December 2, 2003 decision granting Respondent's subsequent summary judgment motion on the remaining claims is also unreported and is reproduced in the Appendix at 75a.

## JURISDICTION

The judgment of the court of appeals was entered on May 16, 2006. Pet. App. 1a. This Court has jurisdiction under 28 U.S.C. § 1254(1).

## STATUTES AND REGULATIONS INVOLVED

21 U.S.C. § 360k provides in part:

**State and local requirements respecting devices**

**(a) General rule**

Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—

> **(1)** which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> **(2)** which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 C.F.R. § 808.1(d) provides in part:

State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect

> devices that are not preempted by section 521(a) of the act [21 U.S.C. § 360k(a)] because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:
>
> (1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices. . . .

## STATEMENT OF THE CASE

This petition arises from a state-law damages suit by Charles and Donna Riegel to recover for injuries suffered by Mr. Riegel from a balloon catheter manufactured by respondent Medtronic, Inc. The court of appeals held that the MDA preempts the Riegels' claims.

Because an understanding of the structure of the MDA is important to understanding this case, Part A below offers a general description of the MDA. Part B describes the decision in *Medtronic v. Lohr*, in which the Court considered the scope of the MDA's preemption provision. Part C sets forth the facts of this case and the proceedings below.

### A. The Medical Device Amendments

Congress enacted the MDA principally to increase consumer protection by preventing the distribution of dangerous medical devices and by providing a process through which devices could reach the market. H.R. Rep. 853, 94th Cong., 2d Sess. 1-12 (1976); *see* P.L. No. 94-295, 90 Stat. 539 (1976) (codified at 21 U.S.C. § 360c *et seq.*). Introducing the bill on the Senate floor, the bill's principal sponsor stated: "The legislation is written so that the benefit of the doubt is always given to the consumer. After all it is the consumer who pays with his health and his life for medical device malfunctions." 121 Cong. Rec. S6140 (Apr. 17, 1975) (Sen. Kennedy).

Under the MDA, each medical device falls into one of three classes. Class I devices, such as band-aids, are the least risky devices and are subject only to "general controls" applicable to all devices, such as general labeling requirements and good manufacturing practices rules promulgated by the FDA, the agency charged by Congress with implementing the MDA. *See* 21 U.S.C. § 360c(a)(1)(A).

Class II devices, such as hearing aids and tampons, are more likely than class I devices to cause harm if they are defective or misused. *Id.* § 360c(a)(1)(B). The FDA may therefore subject them to "special controls," such as the agency's specific warning language for tampon labeling. *See* 21 C.F.R. § 801.430(c), (d) & (e).

Class III devices—such as the devices at issue here and in *Lohr*—are those that, in general, cannot be marketed until the FDA has found that they present a reasonable assurance of safety and effectiveness. 21 U.S.C. § 360c(a)(1)(C). Marketing

permission granted through this process is known as pre-market approval, or PMA. *Id.* § 360e(b)(1)(A).[2]

Three components of the regulatory structure are relevant to this petition. First, when the FDA approves a manufacturer's PMA application, it does not conclude that the device is free of defect in design or labeling. The FDA does not generate the device's design or labeling, and it does not test or conduct studies of the device. Rather, a device's design and labeling originate with the device manufacturer, on whose data the FDA depends in acting on the PMA application. *See* 21 C.F.R. §§ 814.20, 814.44. When granting PMA, the FDA typically sends a form approval letter reminding the manufacturer of generally applicable obligations under federal regulations. There is nothing device-specific in the form approval letter. And although manufacturers of PMA devices must generally conform their products to the approved design and labeling that they devised, they may make design changes with FDA approval. *Id.* § 814.39(a). They may also make labeling changes to enhance safety, such as strengthening contra-indications and warnings, without pre-approval from the FDA. *Id.* §§ 814.39(d)(1) & (2).

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[2]If the FDA finds that a class III device is "substantially equivalent" to a device marketed prior to the MDA's effective date, or to a device that itself was found to be "substantially equivalent" to a pre-MDA device, that device need not obtain PMA until the FDA issues a regulation requiring PMA for that type of device. 21 U.S.C. §§ 360e(b)(1)(B), 360c(f)(1)(A). The FDA's process for giving marketing approval to such a device is sometimes referred to as the "510(k)" process, after the section of the FDCA under which the marketing request is submitted. *See Lohr*, 518 U.S. at 478.

Second, in a few instances, the FDA has issued device-specific requirements for particular types of devices. For instance, the FDA has issued design requirements for certain laser devices, *id.* § 886.4392, and absorbency testing requirements for tampons, *id.* §§ 801.420, 801.430(f). The FDA has never promulgated any such device-specific requirements for balloon catheters, such as the catheter that caused Mr. Riegel's injuries.

Third, the MDA contains a provision, 21 U.S.C. § 360k(a), that preempts certain state-law "requirements" "with respect to a device" that are "different from, or in addition to," MDA "requirements." Under section 360k(b), the FDA may exempt from preemption state requirements that would otherwise be preempted, and FDA regulations implementing this authority reflect section 360k(a)'s narrow reach. *See generally* 21 C.F.R. § 808.1; *see Lohr*, 518 U.S. at 498 n.18 ("FDA's narrow understanding of the scope of § 360k(a) is obvious from the full text of the regulation[.]"). For instance, FDA regulations provide that an FDA requirement has preemptive effect only when it establishes a device-specific "counterpart" to a "divergent" state-law requirement. 21 C.F.R. § 808.1(d). Likewise, to be preempted, state-law requirements must be "specific." Thus, preemption does not extend to state requirements of "general applicability where the purpose of the requirement relates . . . to other products in addition to devices." *Id.* § 808.1(d)(1).

Approximately 15 years after enactment of the MDA, device manufacturers began to argue that section 360k(a) preempts state damages actions. The legislative history of section 360k(a), however, refers solely to the potential for preemption of state and local laws and regulations. *See* H.R. Rep. No. 853 at 4, 45-46.

### B. The Decision in *Medtronic v. Lohr*

In *Lohr*, plaintiff Lora Lohr and her husband Michael Lohr filed suit under Florida law for damages resulting from an allegedly defective class III pacemaker lead that the FDA had cleared for marketing under its section 510(k) "substantial equivalence" process. *See supra* note 2. This Court held that none of the Lohrs' claims—based on defective design, defective manufacture, and failure to warn—was preempted by the MDA.

**1.** *The Majority Opinion.* The majority opinion in *Medtronic* contains three holdings in which all members of the Court concurred: (1) The MDA does not broadly preempt all state-law damages claims against device manufacturers, *see Lohr*, 518 U.S. at 480 (majority); *id.* at 505 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part); (2) the Lohrs' design-defect claim was not preempted because the FDA had not issued any design specifications for the device in question, *id.* at 492-94 (majority); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part); and (3) a tort claim premised on state-law duties "equal to, or substantially identical to, requirements" imposed under the MDA or FDA regulations is not preempted. *Id.* at 494-97; *id.* at 513 (O'Connor, J., concurring in part and dissenting in part).

By a 5-4 margin, in Part V of the *Lohr* majority opinion, the Court also held that the Lohrs' failure-to-warn and manufacturing-defect claims were not preempted, even if they did more than seek to enforce the federal requirements. The Court looked to the language of the MDA's preemption provision and the FDA's preemption regulations and noted the "overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal

interest." *Id.* at 500. The generality of the FDA's labeling and manufacturing regulations applicable to the pacemaker lead, the Court held, precluded a finding of preemption. Those federal requirements, the Court said, reflect "important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements." *Id.* at 501.

The Court further noted that the Lohrs' damages claims were premised on general state-law duties that did not focus specifically on medical devices. Thus, the Court found that the general state-law duties to use due care in manufacturing and to warn users of potential risks are not the types of requirements that Congress or the FDA feared would impede the FDA's ability to enforce specific federal laws and regulations. Because they were based on general principles of state law, the majority held, such claims were outside of the prohibited category of state-law requirements "with respect to" specific devices within the meaning of section 360k(a). *Id.* at 501-02.[3]

**2.** *The Concurrence.* Justice Breyer filed a concurring opinion stating that, in his view, section 360k(a)'s reference to state-law "requirements" encompasses state-law damages claims. He did not join Parts IV and VI of the lead opinion (*see supra* note 3) because he was not convinced that MDA

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[3]Speaking for a four-Justice plurality, the lead opinion relied on the MDA's language and history to conclude that section 360k(a) was not intended to preempt most, and perhaps any, damages claims. 518 U.S. at 488-91. The plurality found it unnecessary to decide whether section 360k(a) reached any damages claims, however, because, under the majority's more focused analysis, none of the Lohrs' claims was preempted. *Id.* at 502-03.

preemption of damages claims would be "rare." *Id.* at 508. He joined fully, however, in Part V of the majority opinion, discussed immediately above, which demanded specificity on both the state and federal sides of section 360k(a)'s preemption analysis. He stated that the applicable FDA requirements that were related to the Lohrs' claims were not "specific" in any relevant sense and deferred to the FDA's preemption regulation, 21 C.F.R. § 808.1(d), which amplifies the meaning of section 360k(a)'s specificity requirement. 518 U.S. at 505-06. He noted that the language of section 360k(a) reflects principles of conflict preemption, but found no conflict between any federal requirement and any of the Lohrs' claims. *Id.* at 506.

**3.** *The Partial Dissent.* Justice O'Connor dissented in part and concurred in part, joined by Chief Justice Rehnquist and Justices Scalia and Thomas. In her view, state-law damages claims could constitute "requirements" under section 360k(a). *Id.* at 509-11. Although concurring with the majority that the Lohrs' design-defect claim was not preempted, she would have held that the manufacturing-defect and failure-to-warn claims were preempted to the extent that they sought to impose requirements different from those imposed by the FDA's manufacturing and labeling rules. *Id.* at 513-14. She agreed with the majority, however, that the Lohrs' manufacturing-defect and failure-to-warn claims were not preempted to the extent that they alleged violations of federal requirements. *Id.* at 513.

### C. Factual Background and Proceedings Below

This action arose from serious injuries caused by a defective Medtronic balloon catheter. The catheter received marketing approval in 1994 as a supplement to a PMA first

issued in 1988. In 1995 and 1996, Medtronic sought and received approval to make design and labeling changes.

In May 1996, Charles Riegel underwent an angioplasty intended to dilate his coronary artery. His physician used the Medtronic catheter, which burst during the angioplasty. Mr. Riegel developed a complete heart block, and he lost consciousness and blood pressure. Advanced life support was needed to sustain him, and he was rushed to the operating room for emergency coronary bypass surgery. Pet. App. 4a.

The Riegels sued Medtronic, alleging design, labeling, and manufacturing defects and stating negligence, strict liability, and express and implied warranty claims. In January 2002, Medtronic moved for summary judgment based on preemption and to dismiss the express warranty claim for failure to state a claim. In March 2002, the district court granted the summary judgment motion in part, holding that all of the Riegels' claims are preempted except for those based on negligent manufacturing and express warranty. *See id.* at 55a. Following discovery, Medtronic moved for summary judgment on the two remaining claims; the district court granted the motion in a ruling no longer at issue. *Id.* at 75a.

The Riegels appealed the district court's decisions with respect to preemption and the manufacturing defect claim. In a 2-to-1 decision, the Second Circuit affirmed the district court. The majority held that PMA imposes device-specific preemptive "requirements" within the meaning of section 360k(a) and that the Riegels' design and labeling claims are sufficiently "device-specific" to warrant preemption. *Id.* at 25a, 30a. The majority suggested that jury verdicts put manufacturers of PMA devices in an untenable position because compliance with both federal requirements and jury verdicts

might be "impossible." *Id.* at 34a. The court did not attempt to reconcile that statement with the decades of jury verdicts in medical device cases or with this Court's recent decision in *Bates v. DowAgroSciences*, which noted that "an event, such as a jury verdict, that merely motivates an optional decision is not a requirement." 125 S. Ct. 1788, 1799 (2005); *see also Cipollone v. Liggett Group*, 505 U.S. 504, 518 (1992) ("[T]here is no general, inherent conflict between [express] federal preemption of state [regulatory] warning requirements and the continued vitality of state common-law damages actions."); *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185-86 (1988) ("The effects of direct regulation . . . are significantly more intrusive than the incidental effects of such an award provision. . . . Congress may reasonably determine that incidental regulatory pressure is acceptable, whereas direct regulatory authority is not.").

Judge Pooler dissented from the panel's preemption decision. Explaining that express preemption is a question of congressional intent, she noted the complete lack of evidence that Congress intended to preempt damages claims. Pet. App. 46a. She further observed that the idea that damages claims are "unambiguously preempted is 'particularly dubious' considering that it appears that until relatively recently neither the industry nor the FDA thought that such claims were preempted." *Id.* at 46a (citing *Bates*, 125 S. Ct. at 1801). Judge Pooler explained that the majority opinion overlooked "two critical aspects of the preemption analysis: the presumption against preemption and congressional intent," *id.* at 43a, both of which "weigh against a finding of preemption." *Id.* She also observed that "the lack of any device-specific federal requirement [for balloon catheters] makes it impossible" to conduct "a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state

requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations." *Id.* at 50a (quoting *Lohr*, 518 U.S. at 500).

## REASONS FOR GRANTING THE WRIT

### A. The Federal And State Appellate Courts Are Deeply Divided Regarding The Application Of *Medtronic v. Lohr* To The Question Presented.

The decision and dissent below reflect the division among the federal and state appellate courts on the question presented: whether the FDA's grant of PMA for a medical device triggers preemption of state-law damages claims alleging that a manufacturer did not properly design the device and failed to warn of the device's risks. The split in authority is particularly problematic in Illinois, Kentucky, and Iowa, where, if the complaint is filed in or removed to federal court, the plaintiff's claims are expressly preempted, but if the complaint is litigated in state court, there is no preemption. *Compare Mitchell*, 126 F.3d 902 (7th Cir.), *Kemp*, 231 F.3d 216 (6th Cir.), *and Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001), *with Weiland*, 721 N.E.2d 1149 (Ill.), *Niehoff*, 950 S.W.2d 816 (Ky.), *and State ex rel Miller v. New Womyn, Inc.*, 679 N.W.2d 593 (Iowa 2004). Further displaying the division of views on the issue, the decision below and other recent appellate decisions finding preemption have provoked lengthy dissents. *See* Pet. App. 43a (Judge Pooler, dissenting from panel decision); *Horn*, 376 F.3d at 180 (in Third Circuit, Judge Fuentes, dissenting from panel decision); *Brooks v. Howmedica*, 273 F.3d at 799-801 (in Eighth Circuit, Judge Bye, joined by Judge Heaney, dissenting from en banc decision).

As noted above, *Lohr* requires that, before preemption may occur, both the allegedly preemptive federal requirement and the allegedly preempted state-law requirement must be "specific" within the meaning of section 360k(a) and regulations promulgated thereunder. *See* 21 C.F.R. § 808.1(d). As the decision below recognized, Pet App. 23a & n.16, conflicts among the federal and state appellate courts exist with respect to both prongs of *Lohr*'s analytic framework.

1. Looking first to the federal-law side of section 360k(a)'s preemption inquiry, *Lohr* held that, to have preemptive effect under 21 U.S.C. § 360k(a), a federal requirement must be specific. Thus, a specific labeling requirement for a particular type of device might have preemptive effect (*see, e.g.*, 21 C.F.R. § 801.430), in contrast to the comprehensive, but general labeling regulations that the Court held did not have preemptive effect. 518 U.S. at 497-99.

The FDA's criteria for PMA applications are general and do not require devices to be designed or labeled in any particular manner. Accordingly, several courts, including the Eleventh Circuit and the Illinois Supreme Court, have held that PMA does not impose device-specific requirements for purposes of preemption under section 360k(a). *See Goodlin*, 167 F.3d at 1373-77 (11th Cir.); *Weiland*, 721 N.E.2d at 1152-53 (Ill.); *Haidak v. Collagen Corp.*, 67 F. Supp. 2d 21, 23-24 (D. Mass. 1999); *Lakie v. SmithKline Beecham*, 965 F. Supp. 49 (D.D.C. 1997); *Quillen v. American Hosp. Supply Corp.*, 1997 U.S. Dist. Lexis 6974, *14-*15 (N.D. Okla. Mar. 31, 1997); *Sowell v. Bausch & Lomb*, 656 N.Y.S.2d 16, 20-21 (N.Y. App.

Div. 1997); *Walker v. Johnson & Johnson Vision Prods., Inc.*, 552 N.W. 2d 679, 684 (Mich. App. 1996).[4]

Other courts, including the Second Circuit below, have come to the opposite conclusion. *See, e.g.*, Pet. App. 25a; *Horn*, 376 F.3d at 169; *Worthy v. Collagen Corp.*, 967 S.W.2d 360, 376 (Tex. 1998), *cert. denied*, 524 U.S. 954 (1998); *Fry*, 695 A.2d at 516; *Green v. Dolsky*, 685 A.2d 110, 117 (Pa. 1996), *cert. denied*, 520 U.S. 1168 (1997); *Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879, 887-88 (Cal. App. 1997).

2. The split in authority is also profound on the state-law side of *Lohr*'s preemption analysis. The Fifth Circuit, for example, has simply ignored *Lohr*'s holding that damages claims are not preempted if they are premised on general state-law duties that do not focus specifically on medical devices. *See Martin*, 254 F.3d at 582-83. Other post-*Lohr* courts that have found damages claims preempted have dealt with the issue more directly, acknowledging *Lohr*'s majority holding and

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[4]Similarly, two state supreme courts have held that state-law damages claims involving class III devices marketed under the MDA's investigational device approval process (*see* 21 U.S.C. § 360j(g))—which is often a precursor to the PMA process—are not preempted because that process does not establish specific requirements under *Lohr*. *See Connelly v. Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996) (en banc), *cert. dismissed*, 520 U.S. 1260 (1997); *Niehoff v. Surgidev*, 950 S.W.2d at 822. *But see Martin v. Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1095 (6th Cir. 1997) (investigational device process does establish preemptive federal requirements), *cert. denied*, 522 U.S. 1075 (1998). *See also Worthy*, 967 S.W.2d at 374 (noting conflict in appellate authority over preemptive effect of MDA's investigational device provisions and stating that PMA and investigational processes are comparable).

noting that it would, if applied in those cases, require a ruling in favor of the plaintiff. *See, e.g., Papike v. Tambrands, Inc.*, 107 F.3d 737, 742 (9th Cir. 1997). However, those courts, including the Second Circuit below, have refused to follow this portion of the majority opinion on the ground that it is purportedly incompatible with Justice Breyer's concurrence. *See* Pet. App. 21 n.14 & 30-31; *Horn*, 376 F.3d at 174-75; *Papike*, 107 F.3d at 742; *Mitchell*, 126 F.3d at 912; *see also Steele*, 63 Cal. Rptr. at 887; *Fry*, 695 A.2d at 517.

These rulings are at odds with the decisions of other appellate courts that have held that this Court's majority opinion in *Lohr* meant what it said: State laws of general applicability are not among those laws targeted for preemption by section 360k(a). *See Oja v. Howmedica*, 111 F.3d 782, 789 (10th Cir. 1997) (notwithstanding existence of specific federal label requirement applicable to the device, no preemption of labeling claim because "Howmedica's general duty to warn users of potential dangers in this case does not have 'the effect of establishing a substantive requirement for a specific device'"); *State ex rel Miller*, 679 N.W.2d at 596 (no preemption of claim against device manufacturer brought under state consumer fraud statute because statute not limited to devices); *Niehoff*, 950 S.W.2d at 822 (no preemption because "Kentucky's strict liability case law and statutes [on which plaintiff relies] are laws of general applicability to all products and fall beyond the scope of the federal preemption under § 360k"); *Walker*, 552 N.W.2d at 686; *Mears v. Marshall*, 944 P.2d 984, 993-95 (Ore. App. 1997), *review denied*, 961 P.2d 217 (Ore. 1998); *Wutzke v. Schwagler*, 940 P.2d 1386, 1391-92 (Wash. App. 1997), *review denied*, 953 P.2d 96 (Wash. 1998); *Baird v. American Med. Optics*, 693 A.2d 904, 909-10 (N.J. Super., App. Div.), *modified and remanded*, 713 A.2d 1019 (N.J. 1997); *Kernats v. Smith Indus. Med. Sys.*, 669 N.E.2d

1300, 1309 (Ill. App.) ("[P]laintiffs' claims emanate from general common-law duties and are not the sort of state requirements that section 360k was intended to preempt."), *appeal denied*, 675 N.E.2d 634 (Ill. 1996), *cert. denied*, 522 U.S. 1044 (1998); *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763, 771-72 (Cal. App. 1996), *review denied*, 1997 Cal. LEXIS 833 (Cal. 1997).

This Court should grant the petition to resolve these conflicts among the federal and state appellate courts.

3. Petitioners acknowledge that the decision below is consistent with the decisions of a majority of courts of appeals to have considered preemption of claims involving PMA devices. This point, however, does not lessen the need for this Court to resolve the persistent conflict. In fact, in a series of cases beginning in the early 1990s, this Court has disagreed with a majority of lower courts as to the effect of an express preemption provision on state-law damages claims. Most recently, in *Bates*, the Court rejected a pesticide manufacturer's sweeping preemption argument and the holdings of nine United States courts of appeals, based on a preemption provision "similarly worded" to section 360k(a). 125 S. Ct. at 1800. Likewise, in *Lohr*, the Court rejected the broad preemption holdings of a majority of the appellate courts that had considered the scope of express preemption under the MDA. *See* 518 U.S. at 492-502; *see also Sprietsma v. Mercury Marine*, 537 U.S. 51, 55 n.3, 63-64 (2002) (rejecting unanimous holdings of federal appellate courts on preemption under Boat Safety Act); *Geier v. American Honda Motor Co.*, 529 U.S. 861, 867-68 (2000) (rejecting holdings of a majority of federal appellate courts on express preemption under Motor Vehicle Safety Act); *Cipollone*, 505 U.S. 504 (rejecting broad preemption holdings of a majority of appellate courts and

finding only limited preemption of damages claims under Federal Cigarette Labeling and Advertising Act).

As these cases indicate, the lower courts have not gotten the message that express preemption provisions are to be narrowly construed. The courts' persistent failure to heed the principles set forth in this Court's recent preemption jurisprudence further demonstrates that the Court's guidance is urgently needed here.

## B. The Second Circuit's Holding Cannot Be Reconciled With *Lohr*.

The decisions holding that PMA preempts damages claims are inconsistent with *Lohr* in three fundamental ways. First, the granting of PMA imposes no device-specific requirement triggering preemption of damages claims under section 360k(a). The PMA process is often more rigorous than the 510(k) marketing process at issue in *Lohr*, 518 U.S. at 478-79 (explaining differences), but it is no more "specific." Both processes apply to class III devices generally, and neither specifies how a product must be designed, manufactured, or labeled. As the Eleventh Circuit has explained, although the PMA process "differs in significant ways from the 510k process," the differences do not give rise to preemption under *Lohr*: "[B]ecause the [PMA] approval itself neither reveals nor imposes any ascertainable substantive prerequisite for approval that we could compare to a purportedly conflicting state requirement, the approval itself does not fit within section 360k(a)(1)'s demand for a specific federal requirement." *Goodlin*, 167 F.3d at 1374, 1376; *see id.* at 1376-77 (FDA's "conditions of [PMA] approval" are generic and thus not preemptive).

Thus, the PMA process embodies no rules similar to the FDA's device-specific labeling rules (*see, e.g.*, 21 C.F.R. § 801.420), or to the hypothetical FDA-required two-inch hearing aid wire discussed in Justice Breyer's *Lohr* concurrence. *Lohr*, 518 U.S. at 504. Moreover, the PMA process itself does not impose specific federal "requirements," as required by section 360k(a), 21 C.F.R. § 808.1(d), and *Lohr*, because the device's specifications originate with the manufacturer, not with the FDA. *Cf. American Airlines, Inc. v. Wolens*, 513 U.S. 219, 228-29 (1995) (preemption clause of Airline Deregulation Act does not shelter airlines from lawsuits "seeking recovery solely for the airline's alleged breach of its own, self-imposed undertakings").

Second, the decisions finding preemption of traditional damages claims involving PMA devices misapprehend *Lohr* because such claims are, without dispute, premised on state-law duties of general applicability. *See Lohr*, 518 U.S. at 501-02. The FDA's long-standing preemption regulation, 21 C.F.R. § 808.1, provides that section 360k(a) "does not preempt State or local requirements of general applicability where the purpose of the requirement relates . . . to other products in addition to devices." 21 C.F.R. § 808.1(d)(1). The FDA's regulation encompasses the Riegels' traditional state-law claims, which are based on generally applicable tort duties. Notably, although the panel majority recognized that *Lohr* "relied upon 21 C.F.R. § 808.1(d)," Pet. App. 19a n.11, the panel failed to consider or apply the regulation.

Third, the court below, like several other courts of appeals, have held that PMA preempts traditional damages claims only by disregarding the *Lohr* majority's analysis and focusing on Justice Breyer's concurrence. *See, e.g.*, Pet. App. 22a n.14 ("There is, undeniably, a certain degree of tension

between Justice Breyer's joining of Part V of the opinion and his separate concurrence. We resolve that tension in favor of the latter."); *Horn*, 376 F.3d at 174-76; *Mitchell*, 126 F.3d at 912. However, even assuming that Justice Breyer's concurrence represents *Lohr*'s holding, the holdings of those courts are inconsistent with the concurrence. Justice Breyer explained that a specific federal regulation demanding a two-inch hearing aid wire would preempt a common-law claim premised on a specific state-law requirement for a one-inch wire. *Lohr*, 518 U.S. at 504 (Breyer, J., concurring). Yet damages claims such as the Riegels', which are based on general state-law duties to design a safe product and to warn of its risks do not involve a specific state-law requirement of this kind. Moreover, they have no counterpart in specific federal requirements. Thus, such claims do not present the kind of direct conflict that concerned Justice Breyer.

More fundamentally, even if the concurrence could be read to favor preemption of generally applicable state-law duties, a lower court has no authority to disregard a majority holding of this Court. Federal courts of appeals are bound to adhere to the controlling decisions of the Supreme Court. *See Hutto v. Davis*, 454 U.S. 370, 375 (1982) ("[U]nless we wish anarchy to prevail within the federal judicial system, a precedent of this Court must be followed by the lower federal courts no matter how misguided the judges of those courts may think it to be."). A separate concurrence, regardless of its content, is not a basis for disregarding a majority opinion of the Supreme Court of the United States. *See Alexander v. Sandoval*, 532 U.S. 275, 285 n.5 (2001) (concurrence does not alter meaning of majority opinion); *Maryland v. Wilson*, 519 U.S. 408, 413 (1997) (concurring opinion does not establish precedent); *see also Agostini v. Felton*, 521 U.S. 203, 217 (1997) (case law not affected by views of five Justices in

concurring opinions). As the Tenth Circuit recognized in *Oja*, 111 F.3d at 788 n.3, the five-justice majority opinion is the binding precedent established in *Lohr*. The appellate courts' misapplication of rules of precedent underscores the need for review here.

### C. The Decision Below Leaves Patients Injured By The Most Risky Devices With No Remedy—A Result Inconsistent With The History Of The MDA.

Review should also be granted because the Second Circuit's and other courts' misinterpretation of *Lohr* and section 360k(a) leaves consumers injured by PMA devices without any remedy in many parts of the country. Where, as here, the federal regulatory scheme does not itself provide a damages remedy, this Court has ascribed preemptive intent to Congress only in the most compelling circumstances. *See English v. General Elec. Co.*, 496 U.S. 72, 87-90 (1990); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984); *see also Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) ("perfectly rational for Congress not to pre-empt common-law claims" when preempting state regulatory law because common-law claims "perform an important remedial role in compensating accident victims"). Such circumstances are not present here.

Congress, when enacting the MDA, made no mention of a desire to preempt common-law claims. Pet. App. 45a-46a (dissent); *see also Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984) ("Congress would [not], without comment, remove all means of judicial recourse for those injured by illegal conduct."). Congress' silence on this point is particularly telling because a major impetus for the MDA was the highly publicized injuries caused by the Dalkon Shield

intrauterine device, which resulted in "well-known, ongoing litigation." Pet. App. 45a (dissent); *Goodlin*, 167 F.3d at 1378 (citing *Lohr*, 518 U.S. at 475-77); *Lohr*, 518 U.S. at 491 (plurality) (Congress was "acutely aware of ongoing product liability litigation" regarding Dalkon Shield). In crafting the MDA, Congress focused on "regulat[ing] medical devices *before* they reached consumers, rather than on addressing their consequences once on the market." *Goodlin*, 167 F.3d at 1378 (emphasis in original). "It would have been inconsistent for the same Congress that enacted these sweeping reforms, intending to make a potentially dangerous industry safer for patients by blocking the admission of defective devices to the market, then to preempt product liability suits when those devices caused injury." *Id.*

Moreover, the notion that section 360k(a) unambiguously preempts state damages claims "is 'particularly dubious' considering it appears that until relatively recently neither the industry nor the FDA thought such claims were preempted." Pet. App. 46a (dissent) (quoting *Bates*, 125 S. Ct. at 1801). More specifically, in 1997, 20 years after enactment of the MDA, the FDA argued to this Court that claims such as the Riegels' were not preempted. *See supra* p.1; *Bates*, 125 S. Ct. at 1801 ("The notion that FIFRA contains a nonambiguous command to pre-empt the types of tort claims that parallel FIFRA's misbranding requirements is particularly dubious given that just five years ago the United States advocated the interpretation that we adopt today."). And the first reported decisions on the medical device industry's attempts to argue that section 360k(a) preempts product liability claims are from 1991, 15 years after enactment. Pet. App. 47a (dissent); *Goodlin*, 167 F.3d at 1381. The notion "that the industry would have ignored its immunity under the MDA for so long after the statute's enactment if Congress, in fact, had intended to provide

immunity in 1976" is far-fetched, *id.*, and further shows the Second Circuit's misunderstanding of the scope of section 360k(a).

## CONCLUSION

The petition for a writ of certiorari should be granted.

Respectfully submitted,

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August 2006

# APPENDIX

UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

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August Term, 2005

Argued: December 15, 2005 Decided: May 16, 2006
Errata Filed: July 20, 2006

Docket No. 04-0412-cv

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CHARLES R. RIEGEL AND DONNA S. RIEGEL,
*Plaintiffs-Appellants*,

—v.—

MEDTRONIC, INC.,
*Defendant-Appellee*.

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Before:
POOLER, KATZMANN, AND B.D. PARKER, *Circuit Judges*

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Appeal from a judgment of the United States District Court for the Northern District of New York (Kahn, *J.*) granting the defendant's motion for summary judgment. Affirmed.

Judge Pooler concurs in part and dissents in part in a separate opinion.

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KATZMANN, *Circuit Judge*:

This case calls upon us to determine, *inter alia*, the scope of the preemption provision set forth in Section 360k(a) of the

1976 Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et. seq.* Specifically, we must decide whether Section 360k(a) preempts common law tort claims regarding medical devices that have entered the market pursuant to the Food and Drug Administration's ("FDA") rigorous premarket approval ("PMA") process. The Supreme Court left open this question in *Medtronic v. Lohr*, 518 U.S. 470 (1996), which held that tort claims as to medical devices that have entered the market pursuant to the far less intensive premarket notification process (often referred to as the "Section 510(k) process") are not preempted by Section 360(k)(a). Since *Lohr*, the majority of circuits addressing this question have held that claims regarding PMA-approved medical devices are, by contrast, preempted. *See Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004); *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001); *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001); *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000); *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997); *but see Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999).

We now join this growing consensus and hold that tort claims that allege liability as to a PMA-approved medical device, notwithstanding that device's adherence to the standards upon which it obtained premarket approval from the FDA, are preempted by Section 360(k)(a). We therefore affirm the district court's (Kahn, *J.*) summary judgment dismissal of the plaintiffs-appellants' strict liability, breach of implied warranty, and negligent design, testing, inspection, distribution, labeling, marketing, and sale claims as to the Evergreen Balloon Catheter, a PMA-approved medical device. With regard to the plaintiffs' remaining claim for negligent manufacturing – which premised liability on the theory that the particular Evergreen Balloon Catheter deployed during plaintiff-appellant Charles Riegel's angioplasty had not been

manufactured in accordance with the PMA-approved standards – we agree with the district court that this claim was not preempted, but that no genuine issue of material fact existed, and thus affirm the district court's summary judgment dismissal of that claim as well.

We note that our preemption analysis is quite limited in scope, affecting the small universe of cases resting on claims alleging liability despite a PMA-approved device's adherence to the standards upon which it secured FDA premarket approval. We take care to explain that we do not hold that all state tort claims as to PMA-approved devices are preempted. Thus, tort claims that are based on a manufacturer's departure from the standards set forth in the device's approved PMA application – such as the Riegels' negligent manufacturing claim – are not preempted.

## I.

### A.

The Evergreen Balloon Catheter is a prescription medical device that defendant-appellee Medtronic, Inc. developed for patients with coronary disease. Physicians use it during angioplasties to open patients' clogged arteries, essentially by inserting the catheter into the clogged vessel, inflating the catheter like a balloon, and then deflating and removing the catheter. The Evergreen Balloon Catheter entered the market pursuant to the PMA process in the mid1990s. Specifically, on August 30, 1994, the FDA approved Medtronic's PMA application for the Evergreen Balloon Catheter, and on April 27, 1995 and April 18, 1996, the FDA approved Medtronic's PMA supplements, which requested approval for revised

labeling for the device. We discuss the PMA process in greater depth *infra* Part III.A.

On May 10, 1996, plaintiff-appellant Charles Riegel underwent a percutaneous transluminal coronary angioplasty, during which his surgeon used an Evergreen Balloon Catheter. The procedure was intended to dilate Riegel's right coronary artery, which had been found to be "diffusely diseased" and "heavily calcified." The device label for the Evergreen Balloon Catheter specifies that its use is contraindicated for patients who have "diffuse or calcified stenoses." During the procedure, Riegel's physician, Dr. Eric Roccario, first attempted to remove the calcium deposits in Riegel's artery with a rotoblator device, and then unsuccessfully inserted several different balloon catheters. Dr. Roccario ultimately inserted the Evergreen Balloon Catheter into Riegel's artery and inflated the device several times, up to a pressure of ten atmospheres. The device label for the Evergreen Balloon Catheter specifies that it should not be inflated beyond the "rated burst pressure" of eight atmospheres. On the final inflation, the Evergreen Balloon Catheter burst, and Riegel began to rapidly deteriorate. He developed a complete heart block, lost consciousness, was intubated and placed on advanced life support, and was rushed to the operating room for emergency coronary bypass surgery. Riegel survived, but according to his Complaint, he suffered "severe and permanent personal injuries and disabilities."

**B.**

Riegel and his wife, Donna, subsequently filed suit against Medtronic in the Northern District of New York, alleging five state common law causes of action: (1) negligence in the design, testing, inspection, manufacture, distribution, labeling,

marketing, and sale of the Evergreen Balloon Catheter; (2) strict liability; (3) breach of express warranty; (4) breach of implied warranty; and (5) loss of consortium.[1] In its amended answer, Medtronic raised the affirmative defense of federal preemption by Section 360k(a) of the 1976 Medical Device Amendments, 21 U.S.C. § 360(c)-(k), to the Food, Drug, and Cosmetic Act, 21 U.S.C. §§ 301 *et. seq,* and subsequently moved for summary judgment on its preemption defense.

In a March 14, 2002 opinion, the district court (Kahn, *J.*) ruled that the Riegels' strict liability claim, breach of implied warranty claim, and all of their negligence claims except for the negligent manufacturing claim were preempted by Section 360k(a), and therefore dismissed all of these claims. The court let stand the Riegels' breach of express warranty claim. Thus, discovery continued on the two remaining substantive claims: the negligent manufacturing claim and the breach of express warranty claim.[2]

Medtronic later moved for summary judgment on these two remaining claims, and on December 2, 2003, the district court granted that motion. The court dismissed the breach of express warranty claim because the Evergreen Balloon Catheter's instructions had clearly disclaimed any express warranty. It dismissed the negligent manufacturing claim on grounds that there was insufficient evidence upon which a reasonable fact-finder could conclude that the Evergreen Balloon Catheter had burst because of negligent manufacture, rather than because

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[1]Because the Riegels are residents of New York State, and Medtronic is a Minnesota corporation, the district court had diversity jurisdiction pursuant to 28 U.S.C. § 1332.

[2]The loss of consortium claim, a derivative claim, was permitted to remain in connection with the two remaining substantive claims.

it had encountered a calcium spicule in Riegel's artery, had been inflated beyond the specified eight atmosphere limit, or some combination thereof.

The Riegels proceeded to file the instant appeal, in which they challenge both the March 14, 2002 and December 2, 2003 summary judgment rulings of the district court. With regard to the March 14, 2002 ruling, they argue that none of their claims was preempted. With regard to the December 2, 2003 ruling, they argue that there were genuine issues of material fact as to their negligent manufacturing claim.[3]

## II.

Initially, we note the applicable standard of review. An order granting summary judgment will be affirmed only when no genuine issue of material fact exists and the movant is entitled to judgment as a matter of law. *See* Fed. R. Civ. P. 56(c); *Island Software & Computer Serv. v. Microsoft Corp.*, 413 F.3d 257, 260 (2d Cir. 2005). With regard to the March 14, 2002 dismissal of many of the Riegels' claims on preemption grounds, there are no disputed facts, and "our task is to determine whether the district court correctly applied the law." *Pagan v. NYNEX Pension Plan*, 52 F.3d 438, 441 (2d Cir. 1995) (internal quotation marks omitted). With regard to the December 2, 2003 dismissal of the Riegels' negligent manufacturing claim, we must decide whether, "construing the evidence in the light most favorable to the non-moving party and drawing all reasonable inferences in its favor," there are any genuine issues of material fact. *SCS Communications, Inc. v. The Herrick Co., Inc.*, 360 F.3d 329, 338 (2d Cir. 2004).

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[3]The Riegels do not, however, challenge the summary judgment dismissal of their breach of express warranty claim.

## III.

### A.

We begin with the preemption issue, for which, at the outset, it is helpful to review the overarching regulatory structure. In 1976, Congress enacted the Medical Device Amendments ("MDA") to the 1938 Food, Drug, and Cosmetic Act, in order to "provide for the safety and effectiveness of medical devices intended for human use." 90 Stat. 539. The MDA established a regulatory structure pursuant to which the Department of Health and Human Services, through the FDA, would regulate medical devices.

Under the MDA, medical devices are categorized into three classes, based on the level of risk that they pose. 21 U.S.C. § 360c(a)(1). First, those devices that "present minimal potential for harm to the user," such as elastic bandages, are classified as "Class I" devices; such devices can be marketed without prior approval and are subject only to "general controls" that cover all medical devices. 21 U.S.C. § 360c(a)(1)(A); *see also* http://fda.gov/cdrh/devadvice/ 3132.html (last visited April 28, 2006); *Lohr*, 518 U.S. at 477. Second, devices that are potentially more harmful, such as powered wheelchairs and infusion pumps, are classified as "Class II" devices." These devices can still be marketed without advance approval, but in addition to being subject to "general controls," they may also be subject to "special controls," such as postmarket surveillance, patient registries, and/or other measures deemed necessary. 21 U.S.C. § 360c(a)(1)(B); *see also* http://fda.gov/ cdrh/devadvice/ 3132.html; *Lohr*, 518 U.S. at 477. Finally, those devices for which "general controls" and "special controls" are insufficient to provide reasonable assurance of safety and effectiveness, and which either "present a potential unreasonable risk of illness or injury" or are "for a use in

supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" are classified as Class III devices. 21 U.S.C. § 360c(a)(1)(C). It is undisputed that the Evergreen Balloon Catheter – the device at issue in this litigation – is a Class III device.[4]

A Class III device is required to undergo "premarket approval to provide reasonable assurance of its safety and effectiveness" before being marketed. 21 U.S.C. § 360c(a)(1)(C). The premarket approval, or "PMA," process is lengthy and rigorous. *See Lohr*, 518 U.S. at 477 (describing the PMA process as a "rigorous one," and noting that the FDA spends an average of 1,200 hours on each PMA submission). The manufacturer must submit a detailed PMA application that contains full reports of all investigations of the safety and effectiveness of the device; a full statement of the components, ingredients, properties, and principles of operation of the device; a full description of the methods used in the manufacture and processing of the device; information about performance standards of the device; samples of the device; specimens of the proposed labeling for the device; and any other relevant information. 21 U.S.C. § 360e(c).

There is significant opportunity for interaction between the FDA and the manufacturer over the course of the PMA process. Typically, the initial PMA application must include data from clinical investigations to establish the safety and effectiveness of the device, 21 C.F.R. § 814.20(b)(6)(ii); the manufacturer cannot even conduct such a clinical investigation in the first place without FDA permission, 21 C.F.R. § 812.1(a). The

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[4]Other examples of Class III devices include replacement heart valves and implanted cerebella stimulators. *See* http://fda.gov/cdrh/dev advice/3132.html.

results of such clinical investigations, in turn, must be included by the manufacturer in the PMA application, along with all of the information described above. *See* 21 C.F.R. § 814.20; 21 U.S.C. § 360e(c). The FDA then reviews the submission to determine whether it is sufficiently complete to enable a substantive review; if not, the FDA will refuse to file it. 21 C.F.R. § 814.42. After having accepted the PMA for filing, the FDA begins its review, which may involve referring the PMA to an advisory committee. 21 C.F.R. § 814.44; *see also* www.fda.gov/cdrh/devadvice/pma ("Review Process: Overview") (last visited April 28, 2006). On the 100th day after the PMA has been filed, the FDA will, at the applicant's request, meet with the applicant to discuss the status of the application and any deficiencies that need to be addressed. *See* 21 U.S.C. § 360e(d)(3).

Once the FDA has concluded its review, it decides whether or not to approve the device for marketing. This choice is not binary; the FDA has means to impose additional requirements. For example, the FDA can issue an "approvable letter" stating that the FDA believes it will be able to approve the application if specific conditions are agreed to by the applicant. *See* 21 C.F.R. § 814.44(e). Alternatively, if the FDA "believes that the application may not be approved," it can "send the applicant a not approvable letter...[that] will describe the deficiencies in the application...and, where practical, will identify measures required to place the PMA in approvable form." 21 C.F.R. § 814.44(f). The FDA thus has quite broad authority to approve, deny, and effectuate modifications of an application throughout the PMA process.

In the end, once the FDA has approved a medical device through the PMA process, the applicant is required to comply with the standards in the PMA approval order. 21 C.F.R.

§ 814.80 ("A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device."). Any changes that the applicant believes could affect the safety or effectiveness of the device must be submitted, via a "PMA supplement," to the FDA for approval. 21 C.F.R. § 814.39(a) ("After FDA's approval of a PMA, an applicant shall submit a PMA supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA. . . .While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include, but are not limited to, the following types of changes if they affect the safety or effectiveness of the device: (1) New indications for use of the device[;] (2) Labeling changes[;] (3) The use of a different facility or establishment to manufacture, process, or package the device[;] (4) Changes in sterilization procedures; (5) Changes in packaging[;] (6) Changes in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device[;] (7) Extension of the expiration date of the device. . . .").

Additionally, the standard FDA "Conditions of Approval" accompanying a PMA order state that continued approval of the PMA "is contingent on the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA." *See* www.fda.gov/devadvice/pma ("Postapproval (Annual) Reports") (last visited April 28, 2006). Such annual reports must (1) identify all changes made to the device (even if those changes did not affect the device's safety or effectiveness and therefore did not first require submission of a PMA supplement), 21 C.F.R. § 814(b)(1); (2) contain a summary and

bibliography of any "unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant," 21 C.F.R. § 814(b)(2)(i); and (3) contain a summary and bibliography of any "reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant," 21 C.F.R. § 814(b)(2)(ii). The standard PMA "Conditions of Approval" also require the manufacturer to submit an "Adverse Reaction Report" or "Device Defect Report" to the FDA within ten days after it receives or has knowledge of information concerning (1) "a mixup of the device or its labeling with another article"; (2) "any adverse reaction attributable to the device that has not been addressed by the device's labeling or is occurring with unexpected severity or frequency"; or (3) "any significant chemical, or other change or deterioration in the device or any failure of the device to meet the specifications established in the PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling." *See* www.fda.gov/devadvice/pma ("Adverse Reaction and Device Defect Reporting").[5] The FDA may also impose other requirements on manufacturers as a condition of PMA

[5]Manufacturers of PMA-approved devices are also fully subject to the FDA's general Medical Device Reporting Regulation, 21 C.F.R. § 803 *et. seq.*, which requires all manufacturers of medical devices to report to the FDA within 30 days of learning from any source that one of their devices "(1) may have caused or contributed to a death or serious injury; or (2) has malfunctioned and this device or a similar device that [it] market[s] would be likely to cause or contribute to a death or serious injury, if the malfunction were to recur." 21 C.F.R. § 803.50. In the event that a manufacturer learns that a reportable event "necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health," it is required to submit a report to the FDA within five days. 21 C.F.R. § 803.53.

approval, such as restrictions on the sale or distribution of the device; continuing evaluation; prominent display of warnings; maintenance of records according to specifications deemed necessary by the FDA; batch testing; and any other requirements that the FDA "determines are necessary to provide reasonable assurance, or continued reasonable assurance, of the safety and effectiveness of the device." 21 C.F.R. § 814.82(a). The FDA can impose such requirements either in the initial PMA approval order, by regulation at the time of PMA approval, or by regulation subsequent to approval. *Id.*

The vast majority of Class III medical devices, however, reach the market without ever going through the rigorous PMA process described above. This is because the MDA also includes a "grandfathering" provision that "allows pre-1976 devices to remain on the market without FDA approval until such time as the FDA initiates and completes the requisite PMA." *Lohr*, 518 U.S. at 478. And, in order to "prevent manufacturers of grandfathered devices from monopolizing the market while new devices clear the PMA hurdle, and to ensure that improvements to existing devices can be rapidly introduced into the market," the MDA also allows new devices that are "substantially equivalent" to such pre-existing devices to enter the market without going through the PMA process. *Id.* This "substantial equivalence" route to the market is known as the premarket notification, or "§ 510(k)," process.[6]

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[6]The "§ 510(k)" reference stems from the number of the section in the original Act. *See Lohr*, 518 U.S. at 478. In addition to covering devices that are substantially equivalent to pre-1976 devices, the § 510(k) process also covers devices that are substantially equivalent to other devices not subject to the PMA process, *e.g.*, because those devices were reclassified from Class III to Class I or II. *See* http://www.fda.gov/cdrh/devadvice/314.html (last visited April 28, 2006).

In its decision, the *Lohr* Court noted that the § 510(k) premarket notification process has become the means by which most new medical devices enter the market. *Id.* at 479. This observation holds true with full force today. Indeed, from the FDA's website, it appears that in the fiscal year 2005, out of the 3,180 new Class III devices that were permitted to enter the market through either the § 510(k) or PMA processes, 3,148 of them went through the § 510(k) process and only 32 went through the PMA process.[7] In other words, in 2005, approximately ninety-nine percent of such devices went through the § 510(k) process and only *one percent* went through the PMA process.

As the contrasting terms "premarket notification" and "premarket approval" suggest, the § 510(k) process differs dramatically from the PMA process. Unlike the PMA process – which requires reasonable assurance that the new device is itself safe and effective, and ultimately results in the FDA's "approval" of the device – the § 510(k) process simply requires the manufacturer to show that the device is substantially equivalent to, *i.e.*, as safe and effective as, a legally marketed device that did not go through the PMA process. As the Supreme Court stated in *Lohr*, the § 510(k) process was apparently intended simply to "maintain the status quo with

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[7]The FDA's website provides monthly listings of all of the § 510(k)-cleared devices, *see* http://www.fda.gov/cdrh/510khome.html #listing (last visited April 28, 2006) and all of the PMA-approved original devices and supplements, *see* http://www.fda.gov/cdrh/pmapage.html# monthly (last visited April 28, 2006). These webpages, along with related information about recent device approvals by the FDA, can also be accessed via the webpage on the FDA's website entitled "Recent Device Approvals." *See* http://www.fda.gov/cdrh/consumer/mda/ ("Recent Device Approvals") (last visited April 28, 2006). The above numbers were calculated with reference to the website's 2005 monthly listings of § 510(k)-cleared devices and PMA-approved original devices.

respect to the marketing of existing medical devices and their substantial equivalents." *Lohr*, 518 U.S. at 494. To that end, "[t]he § 510(k) notification process is by no means comparable to the PMA process; in contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours." *Id.* at 478-79; *see also Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341, 348 (2001) ("[T]he § 510(k) process lacks the PMA review's rigor: The former requires only a showing of substantial equivalence to a predicate device, while the latter involves a time-consuming inquiry into the risks and efficacy of each device.").

In fact, the FDA regulations explicitly prohibit manufacturers of devices that have reached the market through the § 510(k) process from indicating that the FDA has actually approved their device on the merits, stating that the § 510(k) determination that a device is "substantially equivalent" to a pre-existing, non-PMA-approved device on the market "*does not in any way denote approval of the device.* Any representation that creates an impression of a official approval of a device because of complying with the premarket notification regulations is misleading and constitutes misbranding." 21 C.F.R. § 807.97 (emphasis added).

Once a device has entered the market pursuant to the § 510(k) process, its manufacturer has broader latitude to make changes on its own than does the manufacturer of a PMA-approved device. As the FDA explained in its Amicus Curiae Letter Brief to the Third Circuit in *Horn v. Thoratec*, "[i]n direct contrast to the PMA regime, FDA does not 'approve' changes to a Section 510(k)-cleared device. Rather, the manufacturer simply has to demonstrate that its device is still substantially equivalent to its predicate." *Horn v. Thoratec Corp.*, 376 F.3d 163, 172 (3d Cir. 2004). To that end, whereas

a PMA supplement must be submitted for review and approval by the FDA before *any* change is made that "affect[s] the safety or effectiveness of the device," a § 510(k) supplemental submission is required only where the device "is about to be *significantly* changed or modified in design, components, method of manufacturer, or intended use," 21 C.F.R. § 807.81(a)(3) (emphasis added).[8]

Having summarized the PMA and § 510(k) routes to market set forth by the MDA, we now move to one final aspect of the MDA that is crucial for purposes of this case. The MDA also includes an express preemption provision: Section 360k(a). In relevant part, this provision states as follows:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement–
>
> (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

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[8]As examples of such "significant changes or modifications," the FDA listed a "change or modification in the device that could *significantly* affect the safety or effectiveness of the device," and a "*major* change or modification in the intended use of the device." 21 C.F.R. § 807.81(3)(i)-(ii) (emphasis added).

21 U.S.C. § 360k(a).[9]

The application of Section 360k(a)'s preemption provision to medical devices that have entered the market through the two alternate routes described above – the PMA process and the § 510(k) process – forms the crux of this case.

**B.**

During the several decades following the 1976 enactment of the MDA, the circuit courts grappled with how broadly to construe Section 360k(a)'s preemption of state "requirement[s]" that differed from or added to "requirement[s] applicable under this Act." Could a state requirement be created by state common law, or only by state statutes and other enactments? For that matter, did approval under the PMA process – or, alternatively, clearance under the § 510(k) process or some other expedited process – amount to a requirement under the Food, Drug, and Cosmetic Act with which state law could conflict?

This Court addressed some of these questions in *Becker v. Optical Radiation Corp*, 66 F.3d 18 (2d Cir. 1995). There, we stated that state common law claims that alleged product defects as to a PMA-approved device, notwithstanding that device's compliance with the PMA process, would be preempted by Section 360k(a). We explained:

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[9]The MDA goes on to provide, in Section 360k(b), that "[u]pon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a)" certain State regulations from the preemption provision. 21 U.S.C. § 360k(b). Neither party has argued that Section 360k(b) is applicable here.

> At the premarket stage, pursuant to the MDA, the FDA reviews a device's testing, design specifications, intended use, manufacturing method, performance standards and labeling, and decides whether the device is safe and effective. 21 U.S.C. §§ 360e(c)(1), (2). [The plaintiff's] claims allege defective design, defective manufacture, failure to warn and failure to test. If [the plaintiff] were allowed to pursue these claims, and if she were successful, the common law of New York would impermissibly add requirements in the areas reviewed in the [PMA] process, and thus would impose standards on the [device] which are different from those of the MDA.

*Id.* at 20. The *Becker* Court was not, however, presented with the question of whether common law claims as to § 510(k)-cleared devices would be similarly preempted.

It was this latter question that the Supreme Court considered in *Lohr*, where the plaintiffs brought various state tort law claims in regard to the design, manufacturing, and labeling of a pacemaker that had entered the market pursuant to the § 510(k) process. In the course of assessing whether these plaintiffs' tort law claims would – if successful – result in a state law "requirement" that differed from, or added to, a federal "requirement," a fractured Court reached several conclusions.

All nine justices agreed that the § 510(k) process set forth *no* federal requirements as to the design of medical devices, and that clearance through the § 510(k) process simply reflected the FDA's conclusion that a new device was substantially equivalent to a pre-existing device. Thus, the justices unanimously agreed that design defect claims as to

§ 510(k)-cleared devices would not be preempted by Section 360k(a) of the MDA because there would be no federal requirements with which such claims could conflict. *See Lohr*, 518 U.S. at 493-94 (majority opinion) (stating that clearance via the § 510(k) process "did not 'require' Medtronics' pacemaker to take any particular form for any particular reason; the agency simply allowed the pacemaker, as a device substantially equivalent to the one that existed before 1976, to be marketed without running the gauntlet of the PMA process"); 518 U.S. at 513 (O'Connor, *J.*, concurring in part and dissenting in part) ("I agree with the Court that the Lohrs' defective design claim is not preempted by the FDCA's § 510(k) 'substantial equivalency' process....Because the § 510(k) process seeks merely to establish whether a pre-1976 and a post-1976 device are equivalent, and places no 'requirements' on a device, the Lohrs' defective design claim is not preempted.").[10]

When the justices moved from a consideration of the plaintiffs' design defect claims to their manufacturing and labeling claims, however, they fractured over two issues regarding the interpretation of Section 360k(a)'s preemption of state "requirements" that were "different from, or in addition to, any requirement applicable under this Act." First, the justices diverged over whether the reference to "requirements applicable under this Act" meant that only *device-specific* requirements could give rise to preemption, or instead meant that any FDA requirements could give rise to preemption. Five of the justices – Justices Stevens, Kennedy, Souter, Ginsburg, and Breyer – concluded that only federal device-specific

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[10]Justice O'Connor was joined by Chief Justice Rehnquist, Justice Scalia, and Justice Thomas.

requirements could give rise to preemption.[11] *Id.* at 497-500 (majority opinion); *id.* at 505-07 (Breyer, *J.*, concurring in part and concurring in the judgment). These justices therefore agreed that because the only FDA manufacturing and labeling requirements[12] that covered the pacemaker at issue were general in nature rather than device-specific, the plaintiffs' manufacturing and labeling claims were not preempted. By contrast, the remaining four justices – Justices Rehnquist, O'Connor, Scalia, and Thomas – concluded that even general FDA requirements could give rise to preemption, and therefore dissented, in part, on grounds that the plaintiffs' manufacturing and labeling tort claims as to the pacemaker were preempted by the general FDA manufacturing and labeling requirements. *Id.* at 511-514 (O'Connor, *J.*, concurring in part and dissenting in part).

In addition to their 5-4 split over whether the applicable federal requirement needed to be device-specific, the justices

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[11]In reaching this conclusion, they relied upon 21 C.F.R. § 808.1(d), an FDA regulation stating that "[s]tate and local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device difference [sic] from, or in addition to, the specific Food and Drug Administration requirements."

[12]The relevant labeling regulations were set forth in 21 C.F.R. § 801.109(b) and (c), pursuant to which manufacturers of medical devices must include labeling that "bears information for use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to administer the device can use the device safely. . . ." The relevant manufacturing regulations were set forth in the "Good Manufacturing Practices," or "GMP's," which are set forth in 32 sections of the Code of Federal Regulations. *See Lohr*, 518 U.S. at 497.

also divided – again by a 5-4 margin – over whether a state "requirement," as that term was used in Section 360k(a), could derive from state common law or only from state statutes and regulations. Justices Stevens, Kennedy, Souter, and Ginsburg largely adopted the view that only the latter category would typically give rise to a state requirement for purposes of the MDA, stating in Part IV of the opinion that "when Congress enacted § 360k, it was primarily concerned with the problem of specific, conflicting state statutes and regulations rather than the general duties enforced by common-law actions," *id.* at 489 (plurality opinion), and subsequently stating in part VI of the opinion that "it is apparent that few, if any, common law duties have been preempted by this statute. It will be rare indeed for a court hearing a common-law cause of action to issue a decree that has 'the effect of establishing a substantive requirement for a specific device,'" *id.* at 502-03 (plurality opinion).

Justice Breyer, however, declined to join Parts IV and VI of the opinion, and wrote separately to emphasize that he was "not convinced that future incidents of MDA preemption of common-law claims will be 'few' or 'rare.'" *Id.* at 508 (Breyer, *J.*, concurring in part and concurring in the judgment). He stated, with reference to the Court's prior holding in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992),[13] that "[o]ne can reasonably read the word 'requirement' as including the legal requirements that grow out of the application, in particular circumstances, of a State's tort law." *Id.* at 504. Justice Breyer further illustrated this point with the following hypothetical situation:

> Imagine that, in respect to a particular hearing aid component, a federal MDA regulation requires a 2-inch

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[13]The *Cipollone* decision is discussed in greater depth *infra*.

> wire, but a state agency regulation requires a 1-inch wire. If the federal law, embodied in the "2-inch" MDA regulation, pre-empts the state "1-inch" agency regulation, why would it not similarly pre-empt a state-law tort action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire (say, an award by a jury persuaded by expert testimony that use of more than 1-inch wire is negligent)? The effects of the state agency regulation and the state tort suit are identical....Consequently, I believe that ordinarily, insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action.

*Id.* at 504-05. Finally, Justices Rehnquist, O'Connor, Scalia, and Thomas also adopted the view that, pursuant to *Cipollone*, "[i]f § 360(k)'s [sic] language is given its ordinary meaning, it clearly preempts any state common-law action that would impose a requirement different from, or in addition to, that applicable under the FDCA – just as it would preempt a state statute or regulation that had that effect." *Id.* at 511 (O'Connor, *J.*, concurring in part and dissenting in part). In sum, therefore, five justices endorsed the proposition that a state "requirement," for purposes of the MDA, could stem from state common-law actions as well as from state statutes or regulations.[14]

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[14]We note that although Justice Breyer authored a separate concurrence as to this point, and declined to join Parts IV and VI of the *Lohr* opinion, he did join Part V of the *Lohr* opinion, which included the statements that "the general state common-law requirements in this suit were not specifically developed 'with respect to' medical devices," but would

We thus interpret *Lohr* as setting forth two main principles, each endorsed by five justices, for determining whether a common law tort action over a medical device is preempted by the MDA. First, on the federal side of the analysis, courts must consider whether there are any device-specific federal requirements with respect to the device at hand. If so, courts must then turn to the state side to determine whether there would be a conflict between that device specific federal requirement and "any of the liability-creating premises of the plaintiffs' state-law tort suit." *Lohr*, 518 U.S. at 508 (Breyer, *J.*, concurring in part and concurring in the judgment).

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simply stem from "general state common-law requirements," such as "the general duty of every manufacturer to use due care to avoid foreseeable danger in its products," and that "[t]hese state requirements therefore escape preemption, not because the source of the duty is a judge-made common-law rule, but rather because their generality leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices . . . ." *Id.* at 501-02.

There is, undeniably, a certain degree of tension between Justice Breyer's joining of Part V of the opinion and his separate concurrence. We resolve that tension in favor of the latter. Given that Justice Breyer wrote separately to assert that "the MDA will sometimes preempt a state-law tort suit," *id.* at 503 (Breyer, *J.*, concurring in part and concurring in the judgment), that he was "not convinced that future incidents of MDA pre-emption of common-law claims will be 'few' or rare,'" *id.* at 508, that "insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action," *id.* at 504-05, and – most explicitly – that he "basically agree[d] with Justice O'Connor's discussion of the point and with her conclusion," *id.* at 503, we believe that Justice Breyer's crucial fifth vote endorsed the proposition that a state requirement could stem from a state common law tort action premised on the breach of a standard of care. *See also Horn v. Thoratec Corp.*, 376 F.3d 163, 175-76 (discussing this tension in detail and reaching the same conclusion); *but see id.* at 182-84 and n. 30 (Fuentes, *J.*, dissenting).

Since *Lohr*, the majority of circuits have applied the above-described framework to conclude that common law tort actions as to PMA-approved devices, in contrast to § 510-cleared devices, are preempted by the MDA. *See Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004); *Martin v. Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001); *Brooks v. Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001); *Kemp v. Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000); *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997).[15] These circuits have all concluded that (1) approval through the PMA process, unlike the § 510(k) process, amounts to a federal device-specific requirement, and (2) common law tort actions that allege liability as to a PMA-approved device, notwithstanding that device's compliance with the PMA-approved standards, would conflict with that federal device-specific requirement. *See Horn*, 376 F.3d at 170-179; *Martin*, 254 F.3d at 579-584; *Brooks*, 273 F.3d at 795-799; *Kemp*, 231 F.3d at 225-232; *Mitchell*, 126 F.3d at 911-914. Only the Eleventh Circuit has reached the opposite conclusion, holding that approval through the PMA process does not constitute a federal device-specific requirement. *See Goodlin v. Medtronic*, Inc., 167 F.3d 1367, 1376-77 (11th Cir. 1999).[16]

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[15]The Seventh Circuit recently reaffirmed that conclusion in *McMullen v. Medtronic*, 421 F.3d 482 (7th Cir. 2005).

[16]The Tenth Circuit has also indicated, in a non-PMA context, its agreement with the principle that state common law actions premised on the breach of a general duty of care cannot be preempted by the MDA. *See Oja v. Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1997).

Meanwhile, in the years since *Lohr* was decided, various state courts have divided over this issue. *Compare, e.g., Worthy v. Collagen Corp.*, 967 S.W.2d 360, 376-77 (Tex. 1998) (holding that common-law claims that alleged liability notwithstanding device's adherence to PMA-approved standards were preempted); *Steele v. Collagen Corp.*, 63 Cal. Rptr. 2d 879, 887-88 (Cal. Ct. App. 1997) (same); *Green v. Dolsky*, 685

## C.

We now turn to the instant appeal of the district court's March 14, 2002 order dismissing many of the Riegels' claims on preemption grounds. We note, initially, that our *Becker* decision clearly indicated that tort law claims as to a PMA-approved device would be preempted by Section 360k(a) of the MDA. *See Becker*, 66 F.3d at 20. Because the Supreme Court subsequently spoke to the issue of Section 360k(a)'s preemptive scope in *Lohr*, however, we must revisit the issue to determine whether *Becker* is still good law. *See, e.g., Taylor v. Vt. Dep't of Educ.*, 313 F.3d 768, 782-83 (2d Cir. 2002).

Thus, following the *Lohr* Court, our analysis proceeds in two parts. First, we must consider whether, when a device such as the Evergreen Balloon Catheter obtains approval pursuant to the PMA process, it is subject to a "requirement applicable under this Act," *i.e.*, a federal device-specific requirement. Second, we must analyze the Riegels' tort claims to determine whether there is a conflict between that device-specific requirement and "any of the liability-creating premises of the [Riegels'] state-law tort suit." *Lohr*, 518 U.S. at 508 (Breyer, *J.*, concurring in part and concurring in the judgment).

### 1.

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A.2d 110, 117-18 (Pa. 1996) (same) *with Weiland v. Tele[c]tronics Pacing Sys., Inc.*, 721 N.E.2d 1149, 1152-53 (Ill. 1999) (holding that such claims as to PMA-approved devices were not preempted); *Sowell v. Bausch & Lomb, Inc.*, 656 N.Y.S.2d 16, 20-21 (N.Y. App. Div. 1997) (same); *Wutzke v. Schwaegler, et. al.*, 940 P.2d 1386, 1390-92 (Wash. Ct. App. 1997) (same); *Mears v. Marshall*, 944 P.2d 984, 992-996 (Or. Ct. App.) (same); *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763, 771-773 (Cal. Ct. App. 1996) (same).

We agree with the majority of circuits that have held that the relatively small subset of PMA-approved devices – in contrast to the much larger population of § 510(k)-cleared devices – are subject to federal device-specific requirements. In holding that § 510(k) clearance did not give rise to a federal device-specific requirement, the *Lohr* Court explicitly distinguished between the § 510(k) process and the PMA process, stating that the two processes were "by no means comparable." *Lohr*, 518 U.S. at 478-79. Indeed, the *Lohr* Court expressly emphasized that (1) the § 510(k) process was focused on equivalence rather than safety; (2) the FDA itself stated that § 510(k) clearance did not "denote official FDA approval"; (3) the § 510(k) exemption did not appear to have been "intended to do anything other than maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents"; and (4) § 510(k) clearance could not be viewed as "requir[ing] [the device] to take any particular form for any particular reason." *Lohr*, 518 U.S. at 493-94.

The PMA process utterly diverges from the § 510(k) process in each of these respects. First, although clearance through the § 510(k) process simply means that a device is substantially equivalent to a pre-existing device – which may or may not be safe and effective – approval through the PMA process requires reasonable assurance of the device's substantive safety and effectiveness. Second, whereas § 510(k) clearance does not indicate official FDA approval, the FDA has made clear that approval through the PMA process *does* denote such official approval. Indeed, the FDA explains on its website that "PMA is the most stringent type of device marketing application required by FDA. . . . PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s)." *See* http://www.fda.gov/cdrh/

devadvice/pma/ (last visited April 28, 2006). Third, although the § 510(k) process essentially froze the status quo with respect to pre-1976 devices and their substantial equivalents, the PMA process was created as an entirely new regime for devices that were not substantially equivalent to older devices. Finally, whereas § 510(k) clearance does not reflect the FDA's determination that the device should "take any particular form for any particular reason," *Lohr*, 518 U.S. at 493, the PMA process expressly provides the FDA with the power to require the device to take a particular form in order to be approved as safe and effective. As noted above, once the FDA has concluded its review, it can issue an "approvable letter" stating that the FDA believes it can approve the application if "specific conditions" are agreed to by the applicant. *See* 21 C.F.R. § 814.44(e). Alternatively, if the FDA "believes that the application may not be approved," it can "send the applicant a not approvable letter. . . .[that] will describe the deficiencies in the application...and, where practical, will identify measures required to place the PMA in approvable form." 21 C.F.R. § 814.44(f).

Moreover, once a device has obtained PMA approval, the manufacturer cannot make any changes that might affect the safety and effectiveness of the device without further FDA approval. At that point, therefore, the device is clearly subject to the federal, device-specific requirement of adhering to the standards contained in its individual, federally approved PMA. The Riegels have argued that manufacturers of § 510(k)-cleared devices are also precluded from making changes without FDA approval, and that this did not prevent the *Lohr* Court from finding that § 510(k) clearance imposed no device-specific requirements. But their premise is not entirely accurate. As noted above, manufacturers of § 510(k)-cleared devices have broader latitude to make changes without FDA approval than

do manufacturers of PMAapproved devices, given that they must only obtain approval when making significant changes, *see* 21 C.F.R. § 807.81(a)(3), as opposed to any change that "affect[s] the safety or effectiveness of the device," *see* 21 C.F.R. § 814.39(a). This distinction makes sense: the only issue governing § 510(k) clearance is whether the device is substantially equivalent to a pre-existing device that did not go through the PMA process. Thus, unless a significant change is made to a § 510(k)-cleared device, it will presumably still be substantially equivalent to the pre-existing device, and there is no need for further FDA review. By contrast, PMA approval explicitly signifies the FDA's substantive approval of the device's reasonable safety and effectiveness, as the device is currently constituted, and it therefore naturally follows that any changes to a PMA-approved device that might affect the device's safety and effectiveness will require further FDA approval.

For these reasons, we conclude that the Evergreen Balloon Catheter, a PMA-approved device, was subject to the federal device-specific requirement of complying with the particular standards set forth in its approved PMA application. It is true that, as the dissent states, *see post* at **[52a]**, here the FDA approved Medtronic's PMA application for the Evergreen Balloon Catheter without invoking its power to require additional alterations. As such, the only documents in the record from the FDA to Medtronic are generic letters informing Medtronic that the Evergreen Ballon Catheter has obtained PMA approval and that Medtronic must comply with the generally applicable "Conditions of Approval" governing all PMA devices. We believe, however, that this is not relevant to the analysis. Had the FDA believed that the Evergreen Balloon Catheter, as constituted at the time Medtronic submitted its PMA application for the device, was not reasonably safe and effective, it certainly would have had the power to condition

PMA approval on implementation of the changes that the FDA believed were necessary. Alternatively, as the dissent points out, the FDA could also have deemed it appropriate to promulgate performance standards applicable to catheters such as the Evergreen Balloon Catheter, pursuant to 21 C.F.R. § 861.1(b)(3). *Post* at **[52a]**. Apparently, however, the FDA concluded that the Evergreen Balloon Catheter was safe and effective as currently constituted. It would be illogical to hold that because the FDA, after rigorous review, deemed the PMA application for the Evergreen Balloon Catheter acceptable in its present form, the Evergreen Balloon Catheter is less subject to a device-specific regulation than are devices whose initial PMA applications are inadequate and which obtain PMA approval only after significant back-and-forth with the FDA. Once the PMA process is complete, all PMA-approved devices are subject to the same federal device-specific regulation: complying with the standards set forth in their individual approved PMA applications.

The Riegels have also argued that with regard to their failure-to-warn claim relating to the labeling of the Evergreen Balloon Catheter, there is no applicable federal device-specific requirement because (1) the only federal regulation governing the substance of the Evergreen Balloon Catheter's label was 21 C.F.R. § 801.109, the same general regulation that the *Lohr* Court found not to be sufficiently device-specific to warrant preemption of the labeling claims as to the § 510(k)-cleared pacemaker device at issue, *see Lohr*, 518 U.S. at 497-501; and (2) under 21 C.F.R. §§ 814.39(d)(1)-(2), manufacturers of PMA-approved devices can make certain labeling changes without pre-approval from the FDA, such as labeling changes that add or strengthen a contraindication, add or strengthen an instruction, or delete misleading, false, or unsupported information. The flaw in this argument is that, unlike in *Lohr*, here the FDA explicitly approved the labeling of the Evergreen

Balloon Catheter through the PMA process. Indeed, when Medtronic wanted to revise the Evergreen Balloon Catheter's label, it submitted PMA supplements that requested approval for those revisions, and the FDA granted that approval. Thus, we need not reach the question of whether, had Medtronic subsequently changed the catheter's label pursuant to the §§ 814.39(d) process that permits certain changes without FDA approval, failure-to-warn claims as to that label would be preempted, because here there is no evidence that Medtronic ever made changes to the catheter's label other than through the PMA process.

Finally, we note the dissent's concern about the FDA's ability to "do an adequate job of ensuring the safety of medical devices," and its discussion of specific instances in which the FDA approved, via the PMA process, medical devices that were later proven unsafe. *Post* at **[48a-50a]**. We agree that it is imperative for the FDA to protect consumers' safety by exercising careful and reasoned judgment both in (1) evaluating whether to grant PMA approval in the first place (and determining which, if any, changes must be made in the device for it to obtain such approval) and (2) reviewing the postapproval annual reports, adverse reaction reports, and device defect reports that must be submitted by manufacturers of PMA-approved devices in order to determine whether the continuation of such approval is appropriate. As a court, we are constrained to observe, however, that the FDA's level of success in carrying out these responsibilities, rather than bearing on the legal question of whether PMA approval reflects a federal device-specific requirement, is ultimately a policy matter for Congress and the Executive to address.

**2.**

Having ruled that the Evergreen Balloon Catheter was subject to the federal device specific requirement of complying with the standards in its approved PMA application, we now move to the question of whether the Riegels' claims would, if successful, result in state "requirements" that differed from or added to those standards. We conclude that they would.

The Supreme Court first addressed the issue of whether a preemption provision's reference to state "requirements" encompasses state common law tort suits, in addition to state statute or other positive enactments, in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). There, in the context of interpreting the preemption provision contained in the Public Health Cigarette Smoking Act of 1969, 15 U.S.C. § 1334(b), a majority of the Court answered that question in the affirmative. *See id.* at 521-22 ("The phrase 'no requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules. . . . [C]ommon-law damages actions of the sort raised by petitioner are premised on the existence of a legal duty, and it is difficult to say that such actions do not impose 'requirements or prohibitions.[']") (plurality opinion); *see also id.* at 548 (Scalia, *J.*, concurring in the judgment in part and dissenting in part).

In *Lohr*, the five justices who endorsed the view that § 360k(a)'s reference to state "requirements" encompassed state common law tort lawsuits explicitly invoked *Cipollone* in reaching that conclusion. *See Lohr*, 518 U.S. at 504-05 (Breyer, *J.*, concurring in part and concurring in the judgment) ("[I]n *Cipollone*. . ., the Court made clear that similar language 'easily' encompassed tort actions because '[state] regulation can be as effectively exerted through an award of damages as

through some form of preventative relief.' This rationale would seem applicable to the quite similar circumstances here.") (internal citations omitted; alteration in original); *id.* at 510-511 (O'Connor, *J.*, concurring in part and dissenting in part) ("We recently addressed a similar question in *Cipollone*. . . .A majority of the Court agreed that state common-law damages actions do impose 'requirements.'. . .That rationale is equally applicable in the present context.").

Since *Lohr*, the Supreme Court has held firm to the view that state "requirements" can be created by state common law actions. Just last year in *Bates v. Dow Agrosciences LLC*, the Court held – in the context of interpreting the Federal Insecticide, Fungicide, and Rodenticide Act's provision that "State[s] shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this Act," 7 U.S.C. § 136v(b) – that the Fifth Circuit had "correctly [held] that the term 'requirements' in § 136v(b) reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties." 125 S. Ct. 1788, 1798 (2005). Thus, the *Bates* Court explained that the plaintiffs' fraud and negligent-failure-to-warn claims, which were premised on a deficiency in the labeling or packaging of the product at issue, would be preempted by FIFRA, unless the duties that the claims implicated were simply equivalent to FIFRA's own misbranding provisions, rather than adding to or differing from the FIFRA provisions. *Id.* at 1800.[17]

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[17]By contrast, the Court held that the plaintiffs' claims for defective design, defective manufacture, and negligent testing were not preempted, because those claims did not relate to the labeling and packaging of the product, and FIFRA's preemption provision only preempted "requirements for labeling or packaging." *Id.* at 1799. The Court acknowledged that the plaintiffs' success on those claims might prompt the manufacturer to alter

We thus conclude that the Riegels' claims for strict liability, breach of implied warranty, and negligent design, testing, inspection, distribution, labeling, marketing, and sale would, if successful, impose state requirements that differed from, or added to, the PMA-approved standards for the Evergreen Balloon Catheter. These claims do not rest on the premise that the particular catheter used during Mr. Riegel's angioplasty deviated from the standards contained in the approved PMA application for the Evergreen Balloon Catheter. Rather, the liability-creating premise of all of these claims is that the Evergreen Balloon Catheter itself, in its present PMA-approved form, is in some way defective and therefore requires modification.

The Riegels assert that a verdict in their favor would simply stem from generally applicable state common law duties, such as the duty to use due care and the duty to inform users and purchasers of about [sic] relevant risks. Therefore, they argue, such a verdict could not possibly create a state "requirement" that adds to, or differs from, any federal device-specific requirements for the Evergreen Balloon Catheter. We disagree. The Supreme Court made clear in *Cipollone*, *Lohr*, and *Bates* that common law actions, which are premised on the alleged violation of a legal duty, do impose requirements. As Justice O'Connor put it in *Lohr*, "state common-law damages actions

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its product in ways that, in turn, would induce the manufacturer to voluntarily make corresponding changes in its label. *Id.* at 1798-99. The Court explained, however, that this did not mean that such claims could be viewed as setting forth labeling and manufacturing requirements: "[a]n occurrence that merely motivates an optional decision does not qualify as a requirement." *Id.* at 1798. The Court also held that the plaintiffs' breach of express warranty claim was not preempted, because that claim asked only that "a manufacturer make good on the contractual commitment that it voluntarily undertook by placing that warranty on its product." *Id.* at 1799.

operate to require manufacturers to comply with common-law duties." *Lohr*, 518 U.S. at 510 (O'Connor, *J.*, concurring in part and dissenting in part). Indeed, a verdict in the Riegels' favor on any of these claims would represent a finding that the Evergreen Balloon Catheter had not adhered to the various state common law duties implicated by those claims, *e.g.*, that its design did not comport with the duty of due care, or that its labeling did not comport with the duty to warn. Such a verdict would clearly differ from the FDA's PMA approval of the device (and its related packaging, labeling, distribution, and so on) as being reasonably safe and effective, and, moreover, from the FDA's prohibition against making any modifications affecting the device's safety and effectiveness without first obtaining FDA approval.

Indeed, such a situation would be quite analogous to the hypothetical situation posed by Justice Breyer in his *Lohr* concurrence, in which, notwithstanding a federal requirement for a 2-inch hearing wire in a particular hearing aid, a plaintiff brought a tort claim relating to the same hearing aid that premised liability on the manufacturer's failure to use a wire that was 1-inch or less. *Lohr*, 518 U.S. at 504 (Breyer, *J.*, concurring in part and concurring in the judgment). Justice Breyer clearly thought that such a claim would be preempted. *Id.* Here, similarly, there is a federal requirement that the Evergreen Balloon Catheter adhere to the standards set forth in its approved PMA application, absent further FDA approval. Yet the Riegels' claims would premise liability on Medtronic's failure to have done something with the Evergreen Balloon Cath[et]er other than adhere to the PMA-approved standards.

In fact, it is unclear what a manufacturer of a PMA-approved medical device would do when faced with such a jury verdict on a plaintiff's common law claims, given that the manufacturer would nonetheless be unable to make any

modifications affecting the device's safety and effectiveness without obtaining further FDA approval. Moreover, it is certainly conceivable that different juries would reach conflicting verdicts about the same medical devices, thus rendering it almost impossible for a device to comply simultaneously with its federal PMA (which, after all, can only change after an extensive process) and with the various verdicts issued by different juries around the country. In this regard, a finding of preemption is consistent with another purpose evident in the MDA's legislative history: its desire to ensure that "innovations in medical device technology are not stifled by unnecessary restrictions," and its corresponding recognition that "if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened." H.R. Rep. No. 94-853, at 12, 45.

As such, although we agree with the dissent's recognition of a general presumption against preemption, and with the dissent's comment that the legislative history of the MDA is silent as to the specific issue of preemption of state tort liability, *see post* at **[43a-47a]**, we believe that the above discussed Supreme Court precedent makes clear that Section 360k(a)'s reference to state "requirements" should be interpreted to encompass state common law actions. We note, too, that the dissent's argument regarding legislative history and intent is far more persuasive with respect to § 510(k)-cleared devices than with PMA-approved devices. As the Supreme Court stated in *Lohr*, the § 510(k) process appears to have been designed to "maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents. That status quo included the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design." *Lohr*, 518 U.S. at 494. By contrast, the PMA regime represented an entirely

new approach of ensuring consumer safety through increased federal regulation and oversight. It is thus much less clear that the continuation of the previous tort remedies in the PMA context is consistent with the MDA's purpose. *See* Benjamin A. Goldberger, *The Evolution of Substantial Equivalence in FDA's Premarket Review of Medical Devices*, 56 FOOD DRUG. L.J. 317, 332-33 (2001) ("Finding preemption for devices that received PMAs while holding that 510(k)'d devices cannot benefit from preemption is consistent entirely with the original purpose of substantial equivalence doctrine. Developed as a method to ensure economic parity between post-enactment and pre-enactment devices, a substantial equivalence finding allows a company to market devices as others did before the MDA, complete with exposure to tort liability. A PMA, on the other hand, brings a device completely within the scope of the federal regulation as Congress had envisioned it, and, thus is preemptive.").

For these reasons, we adhere to the rationale initially set forth by this Court in *Becker*, and hold that the Riegels' strict liability, breach of implied warranty, and negligent design, testing, inspection, distribution, labeling, marketing, and sale claims are preempted by Section 360k(a) of the MDA. We thus affirm the district court's March 14, 2002 order granting summary judgment to Medtronic on these claims on preemption grounds.

By the same token, we agree with the district court's conclusion that the Riegels' negligent manufacturing claim was not preempted, to the extent that it rested on the allegation that the particular Evergreen Balloon Catheter that was deployed during Mr. Riegel's angioplasty had not been manufactured in accordance with the PMA-approved standards. A jury verdict in the Riegels' favor on this claim would not have imposed state requirements that differed from, or added to, the

PMA-approved standards for this device, but would instead have simply sought recovery for Medtronic's alleged deviation from those standards. *See Lohr*, 518 U.S. at 513 (O'Connor, *J.*, concurring in part and dissenting in part) ("Where a state cause of action seeks to enforce an FDCA requirement, that claim does not impose a requirement that is 'different from, or in addition to,' requirements under federal law. To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply, but the requirements imposed on them under state and federal law do not differ. Section 360k does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*.") (emphasis in original).

We conclude this portion of our analysis by emphasizing that – contrary to the dissent's fear that "the decision today will deprive those who were injured by an unreasonably dangerous medical device of any remedy whatsoever," *post* at **[46a]** – the scope of our decision is actually quite limited. As noted above, the vast majority of Class III medical devices enter the market pursuant to the § 510(k) process, not the PMA process. The Supreme Court has already held in *Lohr* that tort claims as to § 510(k)-cleared devices are not preempted. Moreover, our decision today does not even hold that all state tort claims as to PMA-approved devices are preempted. On the contrary, as set forth above, tort claims that are premised on a manufacturer's deviation from the standards set forth in the device's approved PMA application – such as the Riegels' negligent manufacturing claim – are in no way preempted. Only those claims that allege liability despite a PMA-approved device's adherence to those standards are, pursuant to this decision, preempted. As one article recently noted, "[t]his is a relatively small universe of cases." *See* Gregory J. Scandaglia and Therese L. Tully, 59 FOOD DRUG L.J. 245, 263-64 (2004).

We also question the dissent's conclusion that our holding will necessarily remove the incentives for manufacturers of PMA-approved devices to continue improving the safety of their products once they obtain approval and to alert the FDA of the need for changes as new data becomes available. *See post* at **[48a, 53a]**. As a condition of continued approval, manufacturers of PMA-approved products are already required to provide the FDA with annual reports that summarize any "unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices," 21 C.F.R. § 814(b)(2)(i); and any "reports in the scientific literature concerning the device," 21 C.F.R. § 814(b)(2)(ii). Such manufacturers are also specifically required, as a condition of continued approval, to notify the FDA within ten days of any adverse reactions or device defects. *See supra* page [11a]. Additionally, such manufacturers are also likely to be in competition with other manufacturers of similar devices, providing another incentive for them to continue improving their own devices. In any event, we ultimately view this as a policy issue for the legislative and executive branches rather than a legal question. Should Congress conclude that the preemption of the state tort actions at issue in this case creates undesirable incentives for manufacturers of PMA-approved devices, it is entirely free to amend Section 360k(a) to make clear that its reference to state "requirements" does not include state tort actions.

Finally, we note that our conclusion is further supported by the FDA's recent determination that preemption is warranted with respect to this universe of cases, as indicated by the content of the May 14, 2004 amicus curiae brief that the FDA submitted upon request to the Third Circuit in connection with the *Horn* case, which implicated the same issue that we address here. *See* 2004 WL 1143720 (amicus brief); *Horn*, 176 F.3d at 177-79 ("The FDA has clearly expressed its view that PMA

approval in this particular case requires preemption. The FDA conceives of [the plaintiff's] state common law claims as imposing a 'requirement' which is 'different' from that imposed by the FDA in the PMA process, and thus requiring preemption. . . A majority of the Court in *Lohr* emphasized that the FDA is 'uniquely qualified to determine whether a particular form of state law. . .should be pre-empted.'") (quoting *Lohr*, 518 U.S. at 496). It is certainly true that the FDA previously took a different view, but as the Third Circuit noted in *Horn*, "an agency may change its course so long as it can justify its change with a 'reasoned analysis,'" a standard satisfied here. *Id.* (citing *Motor Vehicle Mfrs. Ass'n v. State Farm Mut. Auto. Ins. Co.*, 463 U.S. 29, 42 (1983)).

## IV.

We now turn to the December 2, 2003 order that granted summary judgment to Medtronic on the Riegels' non-preempted negligent manufacturing claim.

The legal framework governing this claim is undisputed. Because the Riegels do not have the actual Evergreen Balloon Catheter that was used during Mr. Riegel's angioplasty, they can prevail only by proving by circumstantial evidence that it must have been defective. As the New York Court of Appeals recently explained, "[i]n order to proceed in the absence of evidence identifying a specific flaw, a plaintiff must prove that the product did not perform as intended and exclude all other causes for the product's failure that are not attributable to defendants." *Speller v. Sears, Roebuck and Co.*, 100 N.Y.2d 38, 41 (N.Y. 2003).

Medtronic, with reference to expert opinions, has argued that the Evergreen Balloon Catheter used during Mr. Riegel's

angioplasty burst not because it was negligently manufactured, but rather because (1) it was inflated to 10 atmospheres, even though the label stated that it should not be inflated more than 8 atmospheres; (2) it was inserted into an artery that was "diffusely diseased" and "heavily calcified," even though the label stated that it should not be used in such instances (because calcium spicules can puncture the catheter); and/or (3) Dr. Roccario used metal stents that could have punctured the catheter.

Thus, to overcome Medtronic's arguments and survive summary judgment, the Riegels had to come forward with competent evidence excluding Medtronic's proferred alternative causes as the actual origin of the catheter's rupture. *See Speller*, 100 N.Y.2d at 42 (holding that where the defendants argued that the fire in question had been caused not by their refrigerator's wiring, but rather by the plaintiff's stove, "[i]n order to withstand summary judgment, plaintiffs were required to come forward with competent evidence excluding the stove as the origin of the fire").

We agree with the district court that the Riegels did not come forward with competent evidence excluding Medtronic's proffered causes as the origin of the rupture. It is undisputed that Dr. Roccario, in performing Mr. Riegel's angioplasty, inflated the balloon catheter to ten atmospheres, which is two atmospheres and approximately 29.4 pounds per square inch beyond the maximum rated burst pressure explicitly specified on the device label. The Riegels have argued, through Dr. Roccario's affidavit, that "exceeding the maximum recommended atmospheres of eight (8) to ten (10) atmospheres was not outside the window of [the device's] testing in laboratory settings. . . and inflations to ten (10) atmospheres was based upon my past experience with the product and was

called for in the circumstances herein presented in order to attempt to obtain the angiographic appearance that I desired rather than what I was presented with at the time and instead of reintroducing still another balloon." Although it may well be that inflating the balloon catheter up to ten atmospheres was the best decision under the circumstances, this does not indicate that the inflation was not the cause of the catheter's rupture.

It is similarly undisputed that Mr. Riegel had heavily calcified arteries, and that the label for the Evergreen Balloon Catheter contraindicated its use in such an instance. Dr. Roccario has stated that "it is all but routine today at this point in the development of the medical science in question for a PTCA [percutaneous transluminal coronary angioplasty] to go forward under such circumstances." Again, however, this does not mean that in this particular instance, we can exclude the calcified nature of Mr. Riegel's artery as a cause for the catheter's rupture. Indeed, Dr. Roccario himself – while stating that "there was simply nothing about the procedures that I undertook or the medical decisions and choices that I made on May 10, 1996 which in my professional medical opinion in any way contributed to the bursting of this particular Evergreen 3.0-20mm balloon" – has not actually opined that the catheter must have burst as a result of a manufacturing defect.

The only affirmative evidence that the Riegels have adduced in support of their claim that the catheter must have had a manufacturing defect is the report of their expert, engineer Ted Milo, who offered the view that based on the nature of Mr. Riegel's injury, the catheter must have burst not longitudinally, but radially, which – in his view – apparently signified a manufacturing defect. The district court found, however, that Milo's conclusion that the catheter had burst radially was based on "sheer surmise and conjecture rather than

on any scientific basis," and therefore found it to be insufficiently substantiated to be admissible as expert testimony. We agree, and thus conclude that the district court did not abuse its discretion in refusing to admit this evidence. *See Raskin v. The Wyatt Co.*, 125 F.3d 55, 65-66 (2d Cir. 1997) (explaining that district court has broad discretion in deciding whether to admit evidence, that we therefore review evidentiary rulings for manifest error, and that this "same standard of review applies to a district court's evidentiary rulings on expert testimony").

The district court identified serious flaws in Milo's expert opinion. First, Milo did not explain the basis of his conclusion that Mr. Riegel's injury was more indicative of a radial failure than a longitudinal failure. Second, even assuming *arguendo* that the balloon burst radially rather than longitudinally, Milo did not explain why a radial failure could not itself result from the causes that Medtronic proffers here: namely, overinflation of the catheter or by punctures caused by calcifications. Indeed, the district court also pointed out that Milo's own exhibit indicated that even some non-longitudinal failures are caused not by manufacturing defects, but rather by overpressurization or punctures from calcified lesions.[18] The Riegels have not responded to this point on appeal. We also note that in his deposition, when Milo was asked for his response to another expert opinion that "the probable cause of rupture of the balloon catheter was not a manufacturing defect, but rather puncture of the balloon by either a spicule of calcium

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[18]We note that Milo seems to have simply assumed that because Dr. Roccario used a rotoblator to remove the calcium deposits from Mr. Riegel's artery before inserting the Evergreen Balloon Catheter, the device's contraindication for patients with calcified arteries "would no longer be relevant." He did not even address the possibility that some calcium spicules could have remained.

in the vessel wall or a portion of the previously implanted metal stents," he responded, "I have no opinion."

Although the Riegels argue that Milo's theories should have been evaluated by a jury rather than the district judge, this Circuit has explained that it is appropriate for the district court to determine the admissibility of scientific evidence and to rely only on admissible evidence in ruling on summary judgment. *See, e.g., Amorgianos v. National Railroad Passenger Corp.*, 303 F.3d 256, 271 (2d Cir. 2002) (affirming grant of summary judgment after district court had ruled the plaintiff's expert report inadmissible); *Raskin*, 125 F.3d at 66 (stating that "an expert's report is not a talisman against summary judgment"). We believe that the district court was well within its discretion in concluding that Milo's opinion was not an admissible expert opinion and therefore could not serve as a basis for demonstrating a manufacturing defect. An expert opinion requires some explanation as to how the expert came to his conclusion and what methodologies or evidence substantiate that conclusion. *See* Fed. R. Evid. 702 ("If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case"). In this case, Milo essentially provided no explanation as to how he had reached his conclusion that the rupture must have been caused by a manufacturing defect, and himself seems to have backed away from this conclusion in his deposition. It was therefore appropriate for the district court to exclude his opinion.

As a result, because there was no competent evidence excluding Medtronic's proffered causes – particularly, encounter with a calcium spicule in the artery and/or the over-inflation of the catheter – as the origin of the rupture of the Evergreen Balloon Catheter, there were no genuine issues of material fact for a jury on this claim. Therefore, we agree with the district court that the Riegels "failed to submit sufficient evidence from which a fair-minded trier of fact [could] reasonably conclude that Plaintiff excluded all other causes of the burst," and affirm the court's December 2, 2003 dismissal of their negligent manufacturing claim.

## V.

For the foregoing reasons, we hereby affirm the district court's March 14, 2002 and December 2, 2003 orders that, collectively, granted summary judgment to Medtronic on all of the Riegels' claims.

POOLER, Circuit Judge, concurring in part and dissenting in part.

The majority today holds that when a device has gone through the PMA process, all state tort claims regarding the design or labeling of that device are preempted. While the majority opinion skillfully negotiates a complex and splintered area of the law, I believe it overlooks two critical aspects of the preemption analysis: the presumption against preemption and congressional intent. Because both these factors weigh against a finding of preemption, I would resolve the close question of whether the PMA process constitutes a device-specific federal requirement in the negative and find that the Riegel's tort claims are not preempted. Therefore, I respectfully dissent.

I.

The Supreme Court has instructed that "[a]lthough our analysis of the scope of the preemption statute must begin with its text, . . . that interpretation is informed by two presumptions about the nature of pre-emption." Medtronic, Inc. v. Lohr, 518 U.S. 470, 485 (1996) (citing Gade v. Nat'l Solid Wastes Mgmt. Ass'n., 505 U.S. 88, 111 (1992) (Kennedy, J., concurring)). First, we begin with "the presumption that state or local regulation of matters related to health or safety is not invalidated" by preemption. Hillsborough Couty v. Automated Med. Labs., Inc., 471 U.S. 707, 715 (1985). Second, "'[t]he purpose of Congress is the ultimate touchstone' of preemption analysis." Cipllone [sic] v. Liggett Group, Inc., 505 U.S. 504, 516 (1992) (quoting Malone v. White Motor Corp., 435 U.S. 497, 504 (1978)).

Out of respect for the fact that "the States are independent sovereigns in our federal system," we assume that "the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." Lohr, 518 U.S. at 485. Thus, where the states have a long tradition of providing a tort remedy to protect their citizens, the presumption against preemption is particularly strong. See Bates v. Dow Agrosciences LLC, 544 U.S. 431, —, 125 S.Ct. 1788, 1801 (2005) ("The long history of tort litigation against manufacturers of poisonous substances adds force to the basic presumption against pre-emption."). "States traditionally have had great latitude under their police powers to legislate as to the protection of the lives, limbs, health, comfort, and quiet of all persons." Lohr, 518 U.S. at 475. In particular, states have generally provided tort remedies to their citizens when they are injured by defective products.

As the majority notes, Congress enacted the MDA "to provide for the safety and effectiveness of medical devices intended for human use." 90 Stat. 539. One major impetus for the legislation was problems with the Dalkon Shield, an intrauterine contraceptive device that resulted in a high percentage of inadvertent pregnancies, serious infections, and even some deaths. Lohr, 518 U.S. at 476; see also H.R. Rep. No. 94-853, at 8 (1976). Concern about better protecting the public from unsafe devices runs throughout the legislative history of the MDA. See, e.g., H.R. Rep. No. 94-853, at 10 ("[P]resent and potential hazards, and the need for reliability and effectiveness of devices necessitates explicit legislation." (quoting the Report of the Cooper Committee, convened in 1969 to study medical devices)). Senator Edward Kennedy, a major proponent of the MDA, noted that "[t]he legislation is written so that the benefit of the doubt is always given to the consumer. After all it is the consumer who pays with his health and his life for medical device malfunctions." 94 Cong. Rec. 10688. Thus, although legislators may have had a secondary concern about stifling innovation through over regulation, see H.R. Rep. No. 94-853, at 12, their primary purpose was clearly to protect consumers from unsafe medical devices.

The legislative history of the MDA provides no indication that Congress considered the preemption of state tort liability or even that Congress had any concern about litigation hampering the development of useful medical devices. See Lohr, 518 U.S. at 490–91 (plurality opinion). Similarly, contemporaneous analyses of the MDA are silent on the possibility of preemption of state tort claims. Id. at 491 n.13. If Congress actually intended to preempt all state tort claims for defective devices, it seems unlikely that such a dramatic change from existing law would go entirely unmentioned, particularly considering the well-known, ongoing litigation over such devices as the Dalkon Shield. Id. at 491. The only discussion

of the preemption provision that I have found indicates that it was primarily focused on preventing state regulatory schemes, which some states had adopted in the absence of federal regulation on the topic. H.R. Rep. No. 94-853, at 45–46. State tort remedies are not mentioned. Id.

"This silence takes on added significance in light of Congress' failure to provide any federal remedy for persons injured by such conduct." Silkwood v. Kerr-McGee Corp., 464 U.S. 238, 251 (1984). It is hard to believe that Congress, while enacting the FDA to protect consumers, intended to preempt all state tort claims, when that result will have such negative consequences for those same consumers. Because the MDA does not provide a federal remedy for injured consumers, the decision today will deprive those who were injured by an unreasonably dangerous medical device of any remedy whatsoever. If the FDA or the manufacturer negligently fails to consider a potential danger posed by a medical device, it is the injured consumer alone who will pay the price. Worse still, because the Supreme Court has found that fraud on the FDA claims are impliedly preempted, see Buckman v. Plaintiffs' Legal Comm., 531 U.S. 341, 348 (2001), even if PMA was obtained through intentional misrepresentation on the part of the manufacturer, by, for example, failing to report studies indicating substantial risks, the injured consumer cannot recover any compensation for her injury. "If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly." Bates, 125 S.Ct. at 1801 (citing Silkwood, 464 U.S. at 251).

Furthermore, the idea that all state tort claims are unambiguously preempted is "particularly dubious" considering it appears that until relatively recently neither the industry nor the FDA thought such claims were preempted. See Bates, 125

S.Ct. at 1801. It was over fifteen years after the MDA was enacted before the industry began to assert preemption based on FDA approval as a defense to state tort suits. See Goodlin v. Medtronic, Inc., 167 F.3d 1367, 1381 (11th Cir. 1999) (noting that Slater v. Optical Radiation Corp., 756 F.Supp. 370 (N.D. Ill. 1991), aff'd, 961 F.2d 1330 (7th Cir. 1992), was one of the earliest cases in which this argument was raised). As recently as 1997, the FDA took the position that common law duties would be preempted only when the FDA has expressly imposed through regulation or order a specific substantive requirement applicable to a particular medical device and the state common law would impose a different or additional requirement on the same device.[19] See Proposed Rule: Medical Devices; Preemption of State Product Liability Claims, 62 Fed. Reg. 65384, 65387 (Dec. 12, 1997); Brief for United States as Amicus Curiae Opposing Writ of Certiorari at 19, Smiths Indus. Med. Sys., Inc. v. Kernats, 520 U.S. 1208 (1997) (No. 96-1405), 1997 WL 33561767.

Traditionally, state tort claims for negligent design or labeling have provided compensation to consumers when the manufacturer knew or should have known that the design of its product posed an unreasonable risk of harm, and the manufacturer fails to improve the design or warn the consumer about the risk. In addition, strict product liability has generally placed the burden of compensating injured users on manufacturers because they are in a better position to insure against the risk and spread that cost among those who benefit from the product. See Ashley W. Warren, Preemption of Claims Related to Class III Medical Devices: Are the Federal

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[19]The majority argues that the agency is free to change its position provided it gives a reasoned analysis. **[Maj. op at 36]** While I assume this is true, it does not undermine the probative value of the agency's prior understanding in discerning congressional intent.

Objectives of Public Health and Safety Furthered or Hindered?, 49 SMU L. Rev. 619, 643 (1996). The finding of preemption here will place that risk entirely on those unfortunate enough to be injured by defective devices. And if manufacturers are not forced to internalize the costs of risks associated with their devices, they will have little incentive to continue to improve the safety of their products once PMA is granted. See Roger W. Bivens, Substantially Equivalent? Federal Preemption of State Common-Law Claims Involving Medical Devices, 74 Tex. L.Rev. 1087, 1120 (1996). This will undoubtedly reduce the resources expended on safety related innovations that would benefit consumers.

These problems might not in reality undermine Congress's intent to protect consumers if the FDA could generally be trusted to do an adequate job of ensuring the safety of medical devices, but there are serious reasons to doubt that this is the case. Even if the influence of the regulated industry over the agency does not undermine the FDA's effectiveness, the FDA may not have adequate resources to genuinely ensure that devices are safe or to properly and efficiently reevaluate approvals as new information becomes available.[20] See Catherine T. Struve, The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation, 5 Yale J. Health Pl'y L. & Ethics 587, 601–07 (2005).

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[20]While it is true, as the majority points out, that if the manufacturer becomes aware of new information regarding the safety of the device, then it is required to report that information to the FDA. **[Maj Op. 35–36]** This does not change the fact that, if all design claims are preempted, the manufacturer need not seek out safety-related innovations and, even in light of data indicating dangers, is free to remain entirely passive about improving safety until the FDA requires it to do so.

Despite the majority's emphasis on the large number of hours spent reviewing each PMA application, the agency's track record indicates these concerns are far from academic. A May 1993 Report from a subcommittee of the House Committee on Energy and Commerce contained several case studies in which the FDA had awarded PMA to unsafe devices, and attributed these failures to an unwillingness or inability on the part of the FDA to compel manufacturers to provide sufficient data and to critically evaluate the data provided. See Less Than the Sum of Its Parts: Reforms Needed in the Organization, Management, and Resources of the Food and Drug Administration's Center for Devices and Radiological Health, Report by the House Subcommittee on Oversight and Investigations of the Committee On Energy and Commerce, at 1–3, 21 (Comm. Print 103-N 1993). For example, the FDA granted PMA to bovine collagen in 1981, despite numerous flaws in the clinical data, including the Company's failure to submit safety information appropriately. Id. at 23. The FDA also failed to take prompt action when the company marketing the device underreported adverse reactions and made unreported, misleading labeling changes. Id. at 24. Because of disputes over procedure between the FDA and the company, it was not until 1990 that the FDA required the company to conduct an analysis of complaints associated with bovine collagen use. Id. at 24. In 1991, the FDA recognized that there was an association between the use of bovine collagen and autoimmune responses, including serious diseases. Id. at 24. The report also includes other examples of the FDA's failure to recognize and respond to risks associated with medical devices. Id. at 21–34. Thus, there is reason for concern if FDA oversight is the only incentive to improve the safety of medical devices.

The majority considers these concerns to be mere policy matters to be left to Congress and irrelevant to the legal

analysis of preemption. **[Maj. op at 28, 36]** I note these issues only to highlight how the majority's holding fails to consider Congress's intent to protect consumers. Because the Supreme Court has instructed us that Congress's intent is the ultimate touchstone of preemption analysis, Cipllone [sic], 505 U.S. at 516, I cannot consider it to be irrelevant to the legal analysis in this case.

If Congress's goal in passing the MDA was to protect consumers, as it seems clear it was, then it is unlikely that it intended to preempt all state tort claims for design or labeling defects whenever a device has gone through the PMA process. Thus, I believe we must recognize a particularly strong presumption against preemption in this case.

II.

With these principles in mind, I turn to whether the particular state tort claims in this case are expressly preempted by Section 360k(a). To make this determination, the Supreme Court has instructed that we conduct "a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations." Lohr, 518 U.S. at 500. Because the lack of any device-specific federal requirement makes it impossible to make such a "careful comparison" with the state tort claims in this case, I would find the Riegels' claims have not been preempted.

I agree with the majority that Lohr requires us first to determine whether the PMA process imposes a device-specific federal requirement on the Evergreen Balloon Catheter. Both the majority and concurring opinions in Lohr relied on the FDA

regulation regarding the scope of preemption under the MDA to reach the conclusion that the federal requirement must be specific. 518 U.S. at 500 (Noting the "overarching concern that preemption occur only where a particular state requirement threatens to interfere with a specific federal interest"); id. at 507 (Breyer, J., concurring) ("[T]he regulation's word 'specific' does narrow the universe of federal requirements that the agency intends to displace at least some state law."). Those regulations state that preemption will occur only when the agency "has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act." 21 C.F.R. § 808.1(d).

Despite the fact that the PMA process focuses on safety and effectiveness while the 510(k) process focuses only on substantial equivalence, whatever requirements, if any, the PMA process imposes on a device are no more *specific* than those imposed by the 510(k) process. See Goodlin, 167 F.3d at 1376; Sowell v. Bausch & Lomb, Inc., 656 N.Y.S.2d 16, 20 (App. Div. 1997). And although the PMA process involves a rigorous and intensive review of a device, neither that review nor eventual approval imposes any ascertainable requirement upon the device that could be compared to any state requirement. See Goodlin, 167 F.3d at 1374–75.

The FDA's approval constitutes no more than a finding that the manufacturer has met the FDA's minimum requirements to show a device's safety and effectiveness. Cf. 21 C.F.R. § 814.45 (listing bases for denial of PMA); see also Goodlin, 167 F.3d at 1375.[21] It does not represent a reasoned

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[21] As discussed above, this was the precise position of the FDA for more than twenty years after the passage of the MDA. See Brief for United States as Amicus Curiae at 15, Smiths Indus. ("[T]hose general [PMA]

consideration and rejection by the agency of possible alternative, safer designs. If the facts showed that the FDA had actually rejected the design improvement advocated by the Riegels' through their tort claims, this might be a different case. However, here the FDA simply issued a generic approval letter. **[JA at 112–13]** Indeed, if the FDA were to determine that a particular device should be subject to substantive requirements, then it has the power to promulgate performance standards to that effect. See 21 C.F.R. § 861.1(b)(3). Such performance standards, unlike PMA, would obviously constitute specific federal requirements with preemptive effect.

The majority argues that the device at issue "was subject to the federal device-specific requirement of complying with the particular standards set forth in its approved PMA application." **[Maj. Op. at 26]** To support this proposition, the majority places substantial reliance on the fact that, once PMA has been granted, the manufacturer cannot make any changes that affect the safety and effectiveness of the device without further FDA approval. **[Maj. Op. at 25]** Yet, because the manufacturer always retains the ability to submit a PMA supplement to request approval of changes, see 21 C.F.R. § 814.39(a), the FDA cannot realistically be said to have *required* a manufacturer not to adopt a specific change until the manufacturer requests approval and is rejected. In fact, a manufacturer can even make certain changes that would enhance safety prior to getting FDA approval. See id. §814.39(d). Thus, I simply cannot conclude that "complying with the particular standards set forth in its approved PMA application" constitutes a specific federal requirement. The FDA "did not 'require' [the Evergreen Balloon Catheter] to

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criteria establish minimum standards that do not displace state law standards of care of common law duties respecting the medical device.").

take any particular form for any particular reason." Lohr, 518 U.S. at 493.

Treating a specific design or label as a requirement when the FDA might well approve a change as an improvement in safety removes any incentive for manufacturers to promptly alert the FDA to the need for changes as new safety data becomes available. See Brooks v. Howmedica, Inc., 273 F.3d 785, 800–01 (8th Cir. 2001) (in banc) (Bye, J., dissenting) (arguing there should be no preemption of claim premised on the failure to warn about risk discovered after PMA when no labeling change was sought); see also Bates, 125 S.Ct. at 1802 ("[T]he specter of damage actions may provide manufacturers with added dynamic incentives to keep abreast of all possible injuries stemming from use of their product so as to forestall such actions through product improvement.").

For the same reasons, the majority's attempt to distinguish the limitation on changes after Section 510(k) approval, which was found not to create a requirement in Lohr, is unpersuasive. The fact that, after PMA, FDA approval is required for any change affecting the safety or effectiveness of the device, rather than only for a significant change, does not make the federal requirement any more specific nor does it mean the manufacturer is required not to make changes to improve the safety of the device.

III.

Because I would find the PMA process does not impose any federal device-specific requirement, there is no need for me to reach the question of whether state tort claims would be preempted by such a requirement. The majority finds the Riegels' claims for negligent design, strict product liability,

breach of implied warranty, and loss of consortium have been preempted because PMA requires Medtronic not to alter the design, manufacturing, or labeling of the Evergreen Balloon Catheter. Despite the purpose of the MDA to protect consumers, I agree with the majority that at least some state tort claims could be preempted because they can impose "requirements" that are different from or in addition to the federal requirements. See Bates, 125 S.Ct. at 1798 (holding in the context of a different preemption provision that "the term 'requirements' . . . reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties"). Nevertheless, because there is no specific federal requirement to compare to these state claims, and nothing prevents Medtronic from improving the design, manufacturing, or labeling of the Balloon Catheter, I would not find these claims have been preempted.

IV.

For the foregoing reasons, I respectfully dissent from the majority's finding of preemption. I do agree, however, that summary judgment was properly granted as to the Riegels' negligent manufacturing claim and concur in that portion of the judgment.

UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

CHARLES R. RIEGEL and DONNA S. RIEGEL,

Plaintiffs,

-against-

99-CV-0649 (LEK/RWS)

MEDTRONIC, INC.,

Defendant.

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**MEMORANDUM-DECISION AND ORDER**

## I. BACKGROUND

### A. Procedural History

Before the Court is Defendant's motion for summary judgment based on federal preemption and for dismissal of Plaintiffs' claim of breach of express warranty for failure to state a claim. Plaintiffs filed a complaint against Defendant in this action on April 29, 1999. The complaint sets forth five causes of action, including negligence, strict liability, breach of express warranty, breach of implied warranty, and loss of consortium. In its amended answer, Defendant sets forth as its fifth affirmative defense the doctrine of federal preemption. Ths Court issues an order limiting initial discovery to preemption issues. Discovery on federal preemption has concluded and Defendant has based this motion for summary judgment on its preemption defense.

B. Factual History

In May 1996, Plaintiff Charles Riegel underwent heart treatment as a result of a myocardial infarction. As part of this treatment, an Evergreen Balloon Catheter (the "Catheter"), manufactured by Defendant, was used for a balloon dilation of Plaintiff's coronary artery. During the inflation of the Catheter, the Catheter exploded allegedly causing Plaintiff serious injuries.

## II. DISCUSSION

A. Standard of Review

Federal Rule of Civil Procedure 56 provides that summary judgment is proper where "the pleadings, depositions, answers to interrogatories and admissions on file, together with the affidavits, if any, show that there is no genuine issue as to any material fact and that the moving party is entitled to a judgment as a matter of law." Fed R. Civ. P. 56(c); Celotex Corp. v. Catrett, 477 U.S. 317, 322-24 (1986). Once the moving party meets its initial burden by demonstrating a right to judgment, the nonmovant must go beyond the allegations in his pleadings and set forth specific facts showing that a genuine issue of material fact exists for trial and that a reasonable jury could return a verdict for the non-moving party. Matsushita Elec. Indus. Co. v. Zenith Radio Corp., 475 U.S. 574, 586-87 (1986).[1] Summary judgment must be granted against a plaintiff

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[1] "When moving party has carried its burden under Rule 56(c), its opponent must do more than simply show that there is some metaphysical doubt as to the material facts." Matsushita, 475 U.S. at 586 (footnote omitted).

who fails to demonstrate facts establishing an essential element of his case. Celotex, 477 U.S. at 322-23.

On a motion for summary judgment, all facts must be viewed and all inferences must be drawn "in the light most favorable" to the non-moving party. United States v. Diebold, Inc., 369 U.S. 654, 655 (1962) (per curiam); Bechhoefer v. United States Dep't of Justice DEA, 203 F.3d 57, 59 (2d Cir. 2000). Bald assertions or conjecture unsupported by evidence are insufficient to overcome a motion for summary judgment. Carey v. Crescenzi, 923 F.2d 18, 21 (2d Cir. 1991).

"[W]hen the defendant provides convincing evidence to explain its conduct and the plaintiff's contention consists of purely conclusory allegations fo discrimination, the Court may conclude that no material issue of fact exists and it may grant summary judgment in favor of defendant." Nweke v. Prudential Ins. Co. Of Am., 25 F. Supp.2d 203, 214 (S.D.N.Y. 1998) (citing Stern v. Trustees of Columbia Univ., 131 F.3d 305, 312-14 (2d Cir. 1997)).

B. Law Governing Medical Devices

1. The Medical Device Amendments

The Medical Device Amendments ("MDA") to the Federal Food, Drug and Cosmetic Act ("FFDCA") governs federal approval of medical devices for marketing. The MDA divides medical devices into three categories. Class III medical devices are those used for supporting or sustaining human life, or that are of substantial importance in preventing impairment of human health, or that present a potential unreasonable risk of illness or injury. 21 U.S.C. § 360c(a)(1)(C). The Evergreen

Balloon Catheter is classified as a Class III medical device under the MDA.

In order to be marketed in the United States, Class III medical devices must undergo a Premarket Approval Process ("PMA"). The PMA process is a rigorous process involving the submission of extensive, detailed information regarding the safety and effectiveness of the device under review. The manufacturer must submit the following detailed information regarding the particular device:

> (A) full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not such device is safe and effective;
> (B) a full statement of the components, ingredients, and properties and of the principle or principles of operation, of such device;
> (C) a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and when relevant, packing and installation of such device;
> (D) when identifying reference to any performance standard under section of 360d of this title which would be applicable to any aspect of such device if it were a class II device, and either adequate information to show that such aspect of such device fully meets such performance standard or adequate information to justify any deviation from such standard;
> (E) such samples of such device and of components thereof as the Secretary may reasonable require, except that where the submission of such samples is impracticable or unduly burdensome, the requirement of this subparagraph may be met by the submission of complete information concerning

> the location of one or more such devices readily available for examination and testing;
> (F) specimens of the labeling proposed to be used for such device; and
> (G) such other information relevant to the subject matter of the application as the Secretary, with the concurrence of the appropriate panel under section 360c of this title may require.

21 U.S.C. § 360e(c)(1).

Once a manufacturer has submitted this information, the Food and Drug Administration ("FDA") spends approximately 1,200 hours reviewing the application. If it determines that the manufacturer has provided reasonable assurances of the device's safety, it issues an order allowing the device to be marketed as approved. Any changes or modifications to the labeling, manufacturing or design of the device that affects its safety or effectiveness must be approved by the FDA before being implemented. If unapproved changes are implemented, the FDA's approval of the device may be withdrawn. 21 U.S.C. § 360e(e)(1); 21 C.F.R. § 814.80.

There are a few exceptions to the PMA process under which medical devices may be marketed without any direct inquiry into the device's safety and effectiveness. The MDA contains a grandfather provision, allowing devices on the market prior to 1976 to remain on the market until the FDA has had an opportunity to review the device's safety. 21 U.S.C. § 360e(b)(1)(a). Investigational devices are exempted from the PMA process and submitted to an investifational device exemption ("IDE") process, designed to encourage, "the discovery and development of useful devices intended for human use." 21 U.S.C. § 360j(g). In addition, devices that are

"substantially equivalent" to devices already on the market may avoid the PMA process. 21 U.S.C. § 360e(b)(1)(B). The process by which substantially equivalent devices are marketed is referred to as the "premarket notification" or the "§ 510(k)" process. Under this process, the manufacturer submits limited information about the device and the FDA performs a cursory review of the device, comparing the new device to a preexisting device. While the FDA spends about 1,200 hours on a PMA review, it spends only about 20 hours on a § 510(k) review. See Medtronic. V. Lohr, 518 U.S. 470, 478-79 (1996).

The MDA expressly preempts certain state law requirements in § 360(a), which states that

> Except as provided in subsection (b) of this section, no State or political subdivision of a state may establish or continue in effect with respect to a device intended for human use any requirement–
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device and
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C.§ 360(a).

2. Medtronic v. Lohr

In Lohr, a divided Supreme Court considered whether the MDA preempted state-law based tort claims regarding the design, labeling and safety of a pacemaker that had been approved under the MDA pursuant to the § 510(k) process. A majority of the Justices, following parts of an opinion written by Justice Stevens, found that the plaintiff's state law claims

were not preempted under the circumstances. However, the Court also engaged in an extensive analysis of the MDA and the effect of its preemption provision. The Court split in its analysis of the MDA, with four Justices joining the majority opinion in its entirety, four Justices joining an opinion by Justice O'Connor, concurring in part and dissecting in part, and Justice Breyer drafting his own concurring opinion in which he sides with the majority's outcome but also expresses agreement with some analysis in the O'Connor opinion.

The Stevens majority analyzed § 360(k) in conjunction with 21 C.F.R. 808.1(d) in order to determine the circumstances under which a state-law requirement would be preempted by the MDA. First, the majority found that in order for preemption to apply, the FDA must have established "specific counterpart regulations or there [must be] other specific requirements applicable to a particular device under the [MDA]." Lohr, 518 U.S. at 498. The majority also found that there must be a specific state requirement "with respect to" medical devices and relating to "the safety and effectiveness of the device or to any other matter included in a requirement applicable to the device." Id. at 500. Preemption applies when the state requirements for the device are "different from, or in addition to" the federal requirements for the device. 21 U.S.C. § 360k(a); Id. A majority of the Supreme Court agreed that these general standards apply to determinations of whether a state-law requirement regarding a medical device is preempted by the MDA. However, what constitutes a "requirement," under federal and state law, and the situations in which the requirements are considered to conflict were hotly contested issues among the Justices.

The Supreme Court Justices diverged in their opinions as to whether a common law tort action brought under state law can

be considered a state requirement for preemption purposes under the MDA. A plurality of the Justices, led by Justice Stevens, found that "it will be rare indeed" for a state common law caus of action to be preempted, since such a claim does not establish the necessary "substantive requirement for a specific device." 21 C.F.R. 808.1(d)(6)(ii); Id. at 502-03. However, a majority of the Justices, including the dissenting Justices and Justice Breyer, disagreed. Justice Breyer summarized the views of this majority by stating that "[o]ne can reasonably read the word 'requirement' as including the legal requirements that grow out of the application . . . of a State's tort law." Id. at 503 (Breyer, J., concurring); see also id. at 509 (O'Connor, J., concurring in part and dissenting in part) ("[S]tate common-law damages actions do impose 'requirements' and are therefore pre-empted when such requirements would differ from those imposed by the [MDA]"). State common law actions, therefore, can be considered state "requirements" for purposes of preemption under the MDA. See, e.g., Brooks v. Howmedica, Inc., 273 F.3d 785, 795 (8th Cir. 2001) (analyzing Lohr and noting that a majority of the Justices in that action agreed that state common law claims can be considered state requirements for preemption purposes).

The Lohr decision is generally understood to hold that the MDA preempts common law claims to the extent they conflict with specific federal requirements. See id. In Lohr, the Stevens majority found that there was no conflict between the plaintiff's state common law claims and the federal labeling and manufacturing requirements for the pacemaker at issue, and thus plaintiff's state claims were not preempted by federal law. Lohr, 518 U.S. at 501. The Lohr court reached this decision in large part because the device at issue had been subject only to the minimal, non-safety related § 510(k) process. Section § 510(k) institutes a requirement only that the device at issue be "substantially similar" to a device already on the market. It

does not address the safety of the device. Since the Lohr plaintiffs' common law claims challenged the safety of the device at issue, there was no clear conflict between the plaintiffs' claims and the federal requirements for the device under § 510(k). Although there was no conflict in the Lohr action itself, the Stevens majority implies that safety-related conflicts may arise in other actions. Justice Stevens writes that Lohr is "unlike a case in which the Federal Government has weighed the competing interests relevant to a particular requirement . . . and implemented [its] conclusion via a specific mandate on manufacturers and producers." Id. at 501; see also id. at 493 (noting that the federal requirements in the Lohr case did not cover the safety of the device at issue of "'require' Medtronics' pacemaker to take any particular form for any particular reason," instead the § 510(k) process required Medtronic to comply only with "general standards").

3. Federal Court Decisions Post-Lohr

One issue left unresolved by Lohr is what type of federal rule or regulation constitutes a federal "requirement" for preemption purposes. While the Supreme Court in Lohr did not specifically consider whether the PMA process imposed a specific federal requirements sufficient to preempt state law requirements, a majority of courts following Lohr have found that the PMA process does impose specific federal safety requirements. See, e.g., Martin v. Medtronic, Inc., 254 F.3d 573, 585 (5th Cir. 2001) (finding that state torn claims relating to design defect, negligence and failure to warn are preempted by the MDA when device was subject to PMA process); Mitchell v. Collagen Corp., 126 F.3d 902, 905 (7th Cir. 1997) (reconsidering prior decision in light of Lohr and finding plaintiff's claims of strict liability, negligence and mislabeling preempted by the MDA when device was subject to PMA

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No. 06-179

# In the Supreme Court of the United States

CHARLES R. RIEGEL, *et al.*,

*Petitioners,*

v.

MEDTRONIC, INC.,

*Respondent.*

**On Petition for a Writ of Certiorari to the United States Court of Appeals for the Second Circuit**

## BRIEF FOR THE RESPONDENT IN OPPOSITION

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## QUESTION PRESENTED

Whether 21 U.S.C. § 360k(a) preempts petitioners' state common law damages claims challenging the design, testing, manufacture, distribution, labeling, and marketing of Medtronic's Evergreen Dilatation Balloon Catheter, when that device was granted pre-market approval (PMA) by the Food and Drug Administration (FDA) and when each of petitioners' claims would impose requirements relating to the safety or effectiveness of the device that would be "different from" or "in addition to" the federal requirements embodied in the FDA's pre-market approval of the device.

## RULE 29.6 STATEMENT

Respondent Medtronic, Inc. is a publicly traded corporation and has no corporate parent. No other publicly held company owns 10 percent or more of respondent's stock.

## TABLE OF CONTENTS


| | | Page |
|---|---|---|
| QUESTION PRESENTED | | i |
| RULE 29.6 STATEMENT | | ii |
| TABLE OF AUTHORITIES | | iv |
| STATEMENT | | 2 |
| | A. The regulatory structure of the Medical Device Amendments. | 2 |
| | B. The Evergreen Balloon Dilatation Catheter was subject to extensive regulatory review prior to receiving FDA approval. | 5 |
| | C. Petitioners' case in the lower courts. | 7 |
| REASONS FOR DENYING THE PETITION | | 11 |
| I. | There Is No Reason For This Court To Revisit Its Ruling In *Medtronic, Inc.* v. *Lohr*. | 12 |
| | A. Any disagreements among the lower courts are minimal and diminishing. | 12 |
| | B. The lower courts should be allowed to consider the implications of the FDA's *amicus* brief in *Horn*. | 19 |
| II. | The Decision Below, Finding Preemption Of State Law Claims Based On The Requirements Imposed By The PMA Process, Is Plainly Correct. | 22 |
| CONCLUSION | | 29 |

## TABLE OF AUTHORITIES

**Page(s)**

**CASES**

*American Airlines, Inc.* v. *Wolens*, 513 U.S. 219 (1995) ..... 24

*Auer* v. *Robbins*, 519 U.S. 452 (1997) ..... 21

*Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431 (2005) ..... 18, 19, 27

*Brooks* v. *Howmedica, Inc.*, 535 U.S. 1056 (2002) ..... 1

*Brooks* v. *Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001) ..... 13, 16

*Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001) ..... *passim*

*Connelly* v. *Iolab Corp.*, 927 S.W.2d 848 (Mo. 1996) ..... 15

*Cupek* v. *Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005) ..... 12, 13, 16

*Fry* v. *Allergan Med. Optics*, 695 A.2d 511 (R.I. 1997) ..... 13, 16

*Geier* v. *American Honda Motor Co.*, 529 U.S. 861 (2000) ..... *passim*

*Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) ..... 14, 16, 19

*Green* v. *Dolsky*, 685 A.2d 110 (Pa. 1996) ..... 14, 16

*Horn* v. *Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) ..... *passim*

*Hughes* v. *Cook*, No. 2:06-CV-02027 (W.D. Tenn. Sept. 27, 2006) ..... 22

*Kemp* v. *Medtronic, Inc.*, 534 U.S. 818 (2001) ..... 1

*Kemp* v. *Medtronic, Inc.*, 231 F.3d 216 (6th Cir. 2000) ..... *passim*

## TABLE OF AUTHORITIES—continued

**Page(s)**

*Knisley* v. *Medtronic, Inc.*, 126 S. Ct. 420 (2005) ..... 1
*Martin* v. *Medtronic, Inc.*, 534 U.S. 1078 (2002) ..... 1
*Martin* v. *Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001) ..... 13, 16
*McMullen* v. *Medtronic, Inc.*, 126 S. Ct. 1464 (2006) ..... 1
*McMullen* v. *Medtronic, Inc.*, 421 F.3d 482 (7th Cir. 2005) ..... 13, 16
*Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996) ..... *passim*
*Mitchell* v. *Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997) ..... 13, 16, 24, 29
*Niehoff* v. *Surgidev Corp.*, 950 S.W.2d 816 (Ky. 1997) ..... 15, 16
*Oja* v. *Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997) ..... 16, 17, 18, 19
*Papike* v. *Tambrands Inc.*, 107 F.3d 737 (9th Cir. 1997) ..... 16
*State ex rel. Miller* v. *New Womyn, Inc.*, 679 N.W.2d 593 (Iowa 2004) ..... 16
*Weiland* v. *Telectronics Pacing Systems, Inc.*, 721 N.E.2d 1149 (Ill. 1999) ..... 14, 15, 16, 19
*Worthy* v. *Collagen Corp.*, 967 S.W.2d 360 (Tex. 1998) ..... 13, 16

### STATUTES, RULES, AND REGULATIONS

Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq* ..... 2
21 U.S.C. § 331(e) ..... 23
21 U.S.C. § 351(f)(1) ..... 23
21 U.S.C. § 360(k)(2) ..... 23

## TABLE OF AUTHORITIES—continued

**Page(s)**

Medical Device Amendments (MDA), 21 U.S.C. §§ 360c *et seq* ..... 2
21 U.S.C. § 360c(a)(2) ..... 25
21 U.S.C. § 360c(b)(1) ..... 23
21 U.S.C. § 360c(c)(2) ..... 23
21 U.S.C. § 360c(c)(e) ..... 23
21 U.S.C. § 360e ..... 23
21 U.S.C. § 360e(b) ..... 23
21 U.S.C. § 360e(c) ..... 5
21 U.S.C. § 360e(c)(2) ..... 23
21 U.S.C. § 360e(d)(2) ..... 3, 23
21 U.S.C. § 360e(d)(3) ..... 5
21 U.S.C. § 360e(f) ..... 23
21 U.S.C. § 360j(a) ..... 23
21 U.S.C. § 360j(m) ..... 23
21 U.S.C. § 360k(a) ..... *passim*
21 U.S.C. § 360k(a)(1) ..... 14, 27
21 U.S.C. § 360k(b) ..... 26
21 U.S.C. § 382(a)(2) ..... 23
21 C.F.R. § 808.1(d) ..... 25, 27
21 C.F.R. § 814.20(b)(6) ..... 5, 6
21 C.F.R. § 814.39(a) ..... 6
21 C.F.R. § 814.44(e) ..... 5, 6
21 C.F.R. § 814.80 ..... 6, 15, 23, 24
Final Rule, *Exemptions From Federal Preemption of State and Local Device Requirements: Procedures For Consideration of Applications*, 43 Fed. Reg. 18,661 (May 2, 1978) ..... 26

## TABLE OF AUTHORITIES—continued

**Page(s)**

Final Rule, *Medical Devices*, 45 Fed. Reg. 67,321 (Oct. 10, 1980) ..... 14

Proposed Rules, *Exemptions From Federal Preemption of State and Local Device Requirements: Proposed Procedures for Consideration of Applications*, 42 Fed. Reg. 30,383 (June 14, 1977) ..... 13

S. Ct. R. 10 ..... 14, 16

Fed. R. Civ. P. 12(b)(6) ..... 8

**MISCELLANEOUS**

Brief for United States as *Amicus Curiae*, 2004 WL 1143720, filed in *Horn* v. *Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) ..... *passim*

*FDA Oversight: Medical Devices: Hrg. Before the Subcomm. on Oversight & Investigations of House Comm. on Energy & Commerce*, 97th Cong., 2d Sess. 5 (1982) ..... 28

Gregory J. Scandaglia & Therese L. Tully, *Express Preemption and Premarket Approval Under the Medical Device Amendments*, 59 FOOD DRUG L.J. 245 (2004) ..... 29

H.R. REP. NO. 94-853 (1976) ..... 2, 26, 28

## BRIEF FOR THE RESPONDENT IN OPPOSITION

On at least five occasions in as many years, this Court has denied petitions for certiorari raising issues identical to those presented here. See *McMullen* v. *Medtronic, Inc.*, 126 S. Ct. 1464 (2006); *Knisley* v. *Medtronic, Inc.*, 126 S. Ct. 420 (2005); *Brooks* v. *Howmedica, Inc.*, 535 U.S. 1056 (2002); *Martin* v. *Medtronic, Inc.*, 534 U.S. 1078 (2002); *Kemp* v. *Medtronic, Inc.*, 534 U.S. 818 (2001). The grounds for denying certiorari, already ample when those prior petitions were reviewed, are even stronger today.

Contrary to petitioners' assertion (Pet. 14), the lower courts are *not* "deeply divided" regarding the application of *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996). Quite the opposite. A clear and growing consensus has emerged that—consistent with this Court's teaching in *Lohr*—FDA premarket approval (PMA) of a medical device preempts conflicting state law claims arising from the design, manufacture, and labeling of such a device. Every court of appeals to have considered the issue in the past seven years has concluded, as did the Second Circuit below, that the FDA's vigorous PMA process establishes device-specific federal requirements that, under 21 U.S.C. § 360k(a), preempt state common law damages claims that would effectively create state requirements "different from" or "in addition to" the federal requirements.

Although there is some vestigial inconsistency in the lower courts' interpretations of *Lohr*, the remaining conflict is increasingly stale and likely to disappear even without this Court's intervention. The only cases to hold that state common law damages claims are never preempted by PMA approval were decided nearly a decade ago, shortly after this Court's decision in *Lohr*. Since then, this Court's subsequent decisions in *Geier* v. *American Honda Motor Co.*, 529 U.S. 861 (2000), and *Buckman Co.* v. *Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), have given clear guidance on the proper

interpretation of *Lohr*. Moreover, the United States has since filed an *amicus curiae* brief in *Horn* v. *Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004), setting forth the FDA's considered opinion that, under the relevant FDA regulation, approval of a medical device through the PMA process generally preempts state common law claims arising from the use of such a device. Given *Geier*, *Buckman*, and the government's *amicus* brief in *Horn*, the few lower courts that had initially misinterpreted *Lohr* are likely to revise their aberrant views without further action by this Court.

## STATEMENT

### A. The regulatory structure of the Medical Device Amendments.

In 1976, Congress enacted the Medical Device Amendments (MDA), 21 U.S.C. §§ 360c *et seq.*, to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. §§ 301 *et seq.*, which vastly expanded the authority of the FDA to regulate medical devices. At the same time that it established a comprehensive regulatory regime at the federal level, Congress sought to protect innovations in device technology from being "stifled by unnecessary restrictions." H.R. REP. No. 94-853, at 12 (1976). Specifically, Congress attempted to shield medical devices from the "undu[e] burden[]" imposed by differing state regulation by including in the MDA a "general prohibition on non-Federal regulation." *Id.* at 45. That general prohibition, which also serves to safeguard the uniformity of the federal regulatory scheme, broadly provides that no state may impose "any requirement" relating to the safety or effectiveness of a medical device that "is different from, or in addition to, any requirement applicable * * * to the device" under federal law. 21 U.S.C. § 360k(a).

This Court has twice considered the preemptive scope of the MDA—in *Lohr* and, more recently, in *Buckman*. In a fractured opinion, the *Lohr* Court held that the MDA's express preemption clause did not bar state law tort actions challenging the design, manufacture, or labeling of "Class

III" devices—*i.e.*, devices that either (1) are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or (2) "present[] a potential unreasonable risk of illness or injury," *id.* § 360c(a)(1)(C)(ii)—if those devices had been approved for sale through a simple "premarket notification" under the "510(k)" process as the "substantial[] equivalent" of a device in existence before the passage of the MDA. See *Lohr*, 518 U.S. at 492–494.

Explicitly differentiating the 510(k) notification process, at issue in *Lohr*, from the PMA process at issue here, the *Lohr* Court noted that "[t]he § 510(k) notification process is by no means comparable to the PMA process." 518 U.S. at 478–479. Thus, "[b]efore a new Class III device may be introduced to the market" via the far more exacting PMA process,

> the manufacturer must provide the FDA with a "reasonable assurance" that the device is both safe and effective. See 21 U.S.C. § 360e(d)(2). Despite its relatively innocuous phrasing, the process of establishing this "reasonable assurance" [in the PMA process] is a rigorous one. Manufacturers must submit detailed information regarding the safety and efficacy of their devices, which the FDA then reviews, spending an average of 1,200 hours on each submission.

*Id.* at 477 (citations omitted). The Court contrasted this "rigorous" review with the 20 hours typical for a 510(k) review. *Id.* at 479. Because the device at issue in *Lohr* had been marketed "without running the gauntlet of the PMA process," *id.* at 494, the *Lohr* Court never addressed the preemptive scope of the PMA process.

In finding 510(k) approval not preemptive, the *Lohr* Court laid out a basic framework for analyzing express preemption under the MDA. First, a majority of the Court held

that one must engage in a "careful comparison" of the details of the federal requirements applicable to the device and the state requirements that are arguably preempted. 518 U.S. at 500. Second, a majority of the Court specifically found that state common law tort actions seeking damages *could* impose "requirements" and thus be preempted. See *id.* at 504–505 (Breyer, J., concurring); *id.* at 509 (O'Connor, J., concurring in part and dissenting in part). Finally, a majority of the Court found that only "specific" federal requirements could be preemptive, and only of "specific" state requirements. See *id.* at 500; *id.* at 506–507 (Breyer, J., concurring). Under this framework, the Court determined that approval through the 510(k) process—which "is focused on *equivalence*, not safety" (*id.* at 493 (emphasis in original) (internal quotation omitted)), and which does "not 'require'" a medical device "to take any particular form for any particular reason" (*ibid.*)—did not preempt the state law claims raised by the Lohrs.

Like *Lohr*, *Buckman* addressed preemption when a device had been approved through the 510(k) process. The plaintiffs in *Buckman* alleged that they were injured by a device manufacturer's "fraud on the FDA." But for fraudulent disclosures to the FDA, they claimed, the agency would not have approved marketing of a device and thus plaintiffs would not have been injured. The Court—noting that "although [*Lohr*] can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim" (531 U.S. at 353)—found such claims to be impliedly preempted by the MDA. Fraud on a federal agency, the Court held, was not a matter historically of state concern, and "fraud-on-the-FDA claims would * * * cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Agency, will later be judged insufficient in state court." *Id.* at 351.

### B. The Evergreen Balloon Dilatation Catheter was subject to extensive regulatory review prior to receiving FDA approval.

Both *Lohr* and *Buckman* stressed the "thorough review" (*Buckman*, 531 U.S. at 344; see also *Lohr*, 518 U.S. at 477) that Class III medical devices must undergo before obtaining approval from the FDA pursuant to the PMA process. Prior to receiving FDA approval, the Medtronic Evergreen Balloon Dilatation Catheter (Evergreen Balloon Catheter), a Class III device used for angioplasty on patients with coronary artery disease, underwent this thorough review.

To obtain FDA approval via the PMA process, a manufacturer such as Medtronic

> must submit a detailed PMA application that contains full reports of all investigations of the safety and effectiveness of the device; a full statement of the components, ingredients, properties, and principles of operation of the device; a full description of the methods used in the manufacture and processing of the device; information about performance standards of the device; samples of the device; specimens of the proposed labeling for the device; and any other relevant information.

Pet. App. 8a (citing 21 U.S.C. § 360e(c)). In addition, the manufacturer "must include data from clinical investigations to establish the safety and effectiveness of the device." *Ibid.* (citing 21 C.F.R. § 814.20(b)(6)(ii)). The FDA closely scrutinizes the PMA application. If it is not satisfied with the information provided, it can demand more information. See Pet. App. 9a (citing 21 U.S.C. § 360e(d)(3), 21 C.F.R. § 814.44(e)). The FDA may also refer the application to an outside advisory panel. See *ibid.* (citing 21 C.F.R. § 814.44). If the FDA decides that the device's design, manufacturing methods or labeling should be revised, the agency can require such revisions as a condition of approval. See *ibid.* (citing 21 C.F.R. § 814.44(e)). In any event, if the device is ultimately

approved, "the applicant is required to comply with the standards in the PMA approval order." *Ibid.* (citing 21 C.F.R. § 814.80).

If a manufacturer wishes to make any changes that might affect the safety or efficacy of a device after it has received PMA approval, the manufacturer must submit a PMA Supplement, which is then subject to renewed FDA scrutiny. The proposed changes may be made only if they receive FDA approval. Pet. App. 10a (citing 21 C.F.R. § 814.39(a)). A PMA Supplement is subject to the same standards of review as an initial PMA application. See 21 C.F.R. § 814.39(c) ("[a]ll procedures and actions that apply to an application under § 814.20 also apply to PMA supplements"); see also *Kemp* v. *Medtronic, Inc.*, 231 F.3d 216, 222 (6th Cir. 2000) (noting that the "procedures applicable to a PMA Supplement are the same as those applicable to an original PMA").

In this case, Medtronic's initial submission to the FDA in connection with the Evergreen Balloon Catheter was made in June 1987, when Medtronic filed a PMA application for an antecedent catheter system. A109.[1] That application was granted the following year. *Ibid.* In March 1994, Medtronic submitted a PMA Supplement for the Evergreen Balloon Catheter. A112. As part of that supplemental application, Medtronic submitted "extensive information about the safety and effectiveness" of the device, all of which was "specific to the Evergreen Balloon Catheter." Pet. App. 65a. Thus, Medtronic provided the FDA with design details, clinical test data, proposed product labels, and a precise description of how the catheter would be produced. See *ibid.*; see also A422–A427. On August 30, 1994, the FDA approved Medtronic's application for the Evergreen Balloon Catheter. Pet. App. 3a. The conditions of approval provided that Medtronic was required to submit a PMA Supplement "[b]efore making

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[1] Citations to A___ are to the Appendix filed below.

any change affecting the safety or effectiveness of the device." A116.[2]

**C. Petitioners' case in the lower courts.**

1. Petitioners are Charles Riegel (Riegel) and his wife, Donna. In May 1996, Riegel, who suffers from coronary disease, underwent surgery intended to unclog his right coronary artery. After several unsuccessful attempts using other devices, Riegel's surgeon decided to perform angioplasty using an Evergreen Balloon Catheter. Pet. App. 4a, 76a; see also A106–A107.

During angioplasty, the catheter is inserted into the patient's artery and the balloon near its tip is then inflated to open the clogged vessel. Thereafter, the balloon is deflated and the device is removed. Pet. App. 3a.

The surgeon's decision to use the Evergreen Balloon Catheter on Riegel was directly contrary to the device's FDA-approved labeling. Pet. App. 38a–43a; *id.* at 90a. Prior to his surgery, Riegel was diagnosed as having a "diffusely diseased" and "heavily calcified" right coronary artery. Pet. App. 4a. The FDA-approved labeling specifically warned that use of the Evergreen Balloon Catheter "is contraindicated"—*i.e.*, is inappropriate—in patients having "diffuse or calcified stenoses." Pet. App. 83a. Because calcification is often associated with hard, sharp points within a clogged artery, it increases the likelihood that the balloon will burst when inflated. Pet. App. 82a; see also A237. Thus, Riegel was not an appropriate candidate for the Evergreen Balloon Catheter. Pet. App. 90a.

Even if Riegel had been a proper candidate for the Evergreen Balloon Catheter, the surgeon chose to use the device

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[2] Medtronic subsequently submitted three PMA Supplements in connection with proposed revisions to the design and labeling of the Evergreen Balloon Catheter. Two of those Supplements were approved by the FDA on April 27, 1995; the third was approved on April 18, 1996. See Pet. App. 3a; A45.

in a manner inconsistent with its labeling. The FDA-approved instructions for the device specifically warn that the "[b]alloon pressure should not exceed the Rated Burst Pressure." Pet. App. 83a. The specific model used on Riegel, the 3.0–20 mm Evergreen Balloon Catheter (Pet. App. 76a), has a Rated Burst Pressure of 8 atmospheres (atm). Pet. App. 84a. Despite this fact, which is clearly noted on the FDA-approved labeling, the surgeon inflated the balloon to 10 atm, or 25 percent higher than approved. Pet. App. 83a.

As a result, the balloon burst while inside Riegel's artery. Pet. App. 43a, 90a; see also A235–A241. As a consequence, Riegel had to undergo emergency bypass surgery. He recovered, although he asserts that he suffered lasting injuries. Pet. App. 4a.

2. Petitioners sued Medtronic. Riegel alleged that Medtronic was "negligent in the design, testing, inspection, manufacture, distribution, labeling, marketing, and sale" of the Evergreen Balloon Catheter, that Medtronic had breached express and implied warranties, and that Medtronic was strictly liable for Riegel's alleged injuries. Riegel's wife asserted a derivative claim alleging loss of consortium. Pet. App. 4a–5a; see also A17–A22.

Medtronic moved for summary judgment on the ground that all of petitioners' claims—other than the express warranty claim, which Medtronic moved to dismiss under Fed. R. Civ. P. 12(b)(6)—were preempted under 21 U.S.C. § 360k(a). In a decision issued on March 14, 2002, the district court granted Medtronic summary judgment on the strict liability and implied warranty claims and on each of the negligence claims other than negligent manufacturing, holding that those state-law claims were preempted under § 360k(a). Pet. App. 68a, 71a.

In factual findings that petitioners do not dispute, the district court found that, as part of the PMA process leading to FDA approval of the Evergreen Balloon Catheter, Medtronic had "submitted extensive information about the safety

and effectiveness" of the device. Pet. App. 65a. That information, all of which was "specific to the Evergreen Balloon Dilatation Catheter," included "test data, the results of clinical investigations and design information" as well as "full copies of proposed product labels." *Ibid.* The district court found that "[t]he Catheter's design was specifically approved by the FDA" and—having been determined by the agency "to provide reasonable assurances of safety"—"cannot be changed or modified without FDA approval." Pet. App. 67a. The court also found that the same was true of the device's manufacturing process and labeling, which were "approved by the FDA in their entirety." *Ibid.*

Because Medtronic "was prohibited from changing the FDA-approved design, labeling, or manufacturing methods without further FDA approval," Pet. App. 65a, the district court found that "[t]he FDA's approval under the PMA process imposes standards on the device manufacturer that are fixed and required." Pet. App. 66a. Accordingly, the district court concluded, "[o]nce the FDA approves these specific safety requirements for a device, those requirements constitute a specific federal requirement, as contemplated for preemption purposes under *Lohr*." *Ibid.*

Given the FDA's approval of the catheter's design, manufacturing method, and labeling, the district court further found that a jury verdict holding Medtronic liable for negligent design, improper manufacturing methods, inadequate labeling, or breach of implied warranty "would necessarily impose a standard on [Medtronic] different from that imposed by the FDA" and would thus "conflict with the federal requirements already applicable to the device." Pet. App. 67a–68a.

Consequently, the district court granted Medtronic's motion for summary judgment on preemption grounds except insofar as the Riegels alleged that "the Catheter at issue in this action was not manufactured in accordance with the FDA's requirements as set forth in the PMA process," a

claim that the district court held "the MDA does not preempt." Pet. App. 71a. Subsequently, in a December 2, 2003, decision not at issue here, cf. Pet. 12, the district court granted Medtronic summary judgment on both the negligent manufacturing claim and the breach of express warranty claim, finding no factual basis for either claim. Pet. App. 90a.[3] On December 11, 2003, the district court—having found petitioners' claims to be preempted and/or without factual basis—entered judgment for Medtronic. Pet. App. 90a–91a.

The Riegels appealed the district court's preemption ruling to the Second Circuit, which affirmed the grant of summary judgment in its entirety.

The court of appeals began by noting that the PMA process "is lengthy and rigorous." Pet. App. 8a. Not only is the PMA process "'the most stringent'" form of FDA review, but final "'PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).'" Pet. App. 25a (quoting http://www.fda.gov/cdrh/devadvice/pma/). Moreover, the court of appeals noted, "once a device has obtained PMA approval, the manufacturer cannot make any changes that might affect the safety and effectiveness of the device without further FDA approval." Pet. App. 26a. Thus, the court found, upon receiving PMA approval, "the device is clearly subject to the federal device-specific requirement of adhering to the standards contained in its individual, federally approved PMA." *Ibid.*

Turning to petitioners' claims that the trial court had held to be preempted, the Second Circuit observed:

> These claims do not rest on the premise that the particular catheter used during Mr. Riegel's angioplasty deviated from the standards contained in the ap-

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[3] The district court also dismissed Donna Riegel's derivative loss of consortium claim.

> proved PMA application for the Evergreen Balloon Catheter. Rather, the liability-creating premise of all of these claims is that the Evergreen Balloon Catheter itself, in its present PMA-approved form, is in some way defective and therefore requires modification.

Pet. App. 32a. The court of appeals therefore "conclude[d] that the Riegels' claims for strict liability, breach of implied warranty, and negligent design, testing, inspection, distribution, labeling, marketing, and sale would, if successful, impose state requirements that differed from, or added to, the PMA-approved standards for the Evergreen Balloon Catheter." *Ibid.*

Accordingly, the Second Circuit held that petitioners' "strict liability, breach of implied warranty, and negligent design, testing, inspection, distribution, labeling, marketing, and sale claims are preempted by Section 360k(a)." Pet. App. 35a. In so holding, the court of appeals joined what it described as the "growing consensus" that state-law "claims regarding PMA-approved medical devices are * * * preempted." Pet. App. 2a. At the same time, the Second Circuit emphasized that its "preemption analysis is quite limited in scope, affecting the small universe of cases resting on claims alleging liability despite a PMA-approved device's adherence to the standards upon which it secured FDA premarket approval." Pet. App. 3a.

## REASONS FOR DENYING THE PETITION

Petitioners assert (Pet. 1–3, 15–18) that review is necessary in this case because of the purported disarray in the lower courts over the interpretation of *Medtronic, Inc.* v. *Lohr*. The Court should deny the current petition, as it denied the petitions filed in *McMullen*, *Knisley*, *Brooks*, *Martin*, and

*Kemp*, which raised essentially the same issues.[4] As we explain in Part I.A, the lower courts are in significantly less disarray than petitioners suggest. Moreover, in light of the *amicus* brief recently filed by the United States in *Horn*—as well as this Court's decisions in *Buckman* and *Geier*—any lingering disagreement within the lower courts is now likely to disappear. See Part I.B, *infra*. In any event, given the FDA's specific approval of and corresponding requirements for the Evergreen Balloon Catheter, the Second Circuit's decision is plainly correct. See Part II, *infra*.

## I. There Is No Reason For This Court To Revisit Its Ruling In *Medtronic, Inc.* v. *Lohr*.

### A. Any disagreements among the lower courts are minimal and diminishing.

Petitioners assert that the lower courts are "deeply divided" on the question whether the FDA's approval of a medical device through the PMA process preempts inconsistent state-law damages claims arising from the design, manufacture, and labeling of such devices. Pet. 15–18. Indeed, petitioners assert that there are conflicts as to both whether the PMA process imposes specific federal requirements and whether any duties imposed through state law damages actions can be preempted after *Lohr*. In fact, although a few courts, in outdated opinions, have misinterpreted *Lohr* on each of these issues, the overwhelming weight of authority—including *all* recent authority—favors the Second Circuit's position on each question.

1. On the "federal" side, *Lohr* held that "specific" federal requirements applicable to a device are preemptive under the MDA. See 518 U.S. at 500–501.[5] Based on this Court's

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[4] Three of these prior petitions—the ones filed in *Knisley*, *Martin*, and *Kemp*—were drafted by counsel for petitioners here and were virtually identical to the current petition.

[5] In dissent, four Justices in *Lohr* observed that "[t]he statute makes no mention of a requirement of specificity, and there is no sound basis for

discussion of the "rigorous" nature of the PMA process, and the Court's comparison between the 510(k) process (which "reflect[s] important but entirely generic concerns," *Lohr*, 518 U.S. at 501) and the PMA process (which focuses on "the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements," *ibid.*), the vast majority of courts—and *all* recent decisions—have found that PMA approval and the resultant bar on changes to a FDA-approved device create specific federal requirements that preempt conflicting state common law damages actions. See, *e.g.*, Pet. App. 25a; *McMullen* v. *Medtronic, Inc.*, 421 F.3d 482, 487–488 (7th Cir. 2005); *Cupek* v. *Medtronic, Inc.*, 405 F.3d 421, 424 (6th Cir. 2005); *Horn*, 376 F.3d at 171–173; *Brooks* v. *Howmedica, Inc.*, 273 F.3d 785, 799 (8th Cir. 2001) (en banc); *Martin* v. *Medtronic, Inc.*, 254 F.3d 573, 585 (5th Cir. 2001); *Kemp*, 231 F.3d at 226–227; *Mitchell* v. *Collagen Corp.*, 126 F.3d 902, 911 (7th Cir. 1997); *Worthy* v. *Collagen Corp.*, 967 S.W.2d 360, 376 (Tex. 1998); *Fry* v. *Allergan Med. Optics*, 695 A.2d 511, 516 (R.I. 1997); *Green* v. *Dolsky*, 685 A.2d 110, 117 (Pa. 1996).

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determining that such a restriction on 'any requirement' exists." 518 U.S. at 512 (O'Connor, J., concurring in part and dissenting in part). We agree; in fact, the history of the FDA regulation relied on by the Court clearly shows that the "specificity" gloss was designed simply to ensure that a counterpart federal requirement *must be in existence* before a state requirement is preempted, not that the federal requirement must be device-specific. See Proposed Rules, *Exemptions From Federal Preemption of State and Local Device Requirements: Proposed Procedures for Consideration of Applications*, 42 Fed. Reg. 30,383 (June 14, 1977). However, the petition does not present this question, because even if specificity is required, the FDA's approval of the Evergreen Balloon Catheter through the PMA process, and the corresponding federal prohibition on any changes to the device's design, manufacturing process or labeling, easily satisfy that requirement.

In contrast to the decisions of the Second, Third, Fifth, Sixth, Seventh, and Eighth Circuits, as well as those of the Pennsylvania, Rhode Island, and Texas Supreme Courts, petitioners can identify (at Pet. 15) decisions of only one federal court of appeals and one state supreme court, cf. S. Ct. R. 10, that did not find PMA approval to be preemptive—*Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999), and *Weiland* v. *Telectronics Pacing Systems, Inc.*, 721 N.E.2d 1149 (Ill. 1999). The decisions in these cases, while at odds with the decision below, are old, internally confused, and unlikely to survive even absent this Court's intervention.

For example, the *Goodlin* court found that the PMA process "is clearly specific to the device under review" and that the FDA's Conditions of Approval "constitute specific federal requirements," 167 F.3d at 1376, yet then somehow concluded that the requirements were not "'applicable under [the MDA] to the device,'" *ibid.* (quoting 21 U.S.C. § 360k(a)(1)), and did not establish "a specific requirement that applies to a particular device," *id.* at 1377. The decision is not only internally inconsistent and factually incorrect, but also contrary to *Lohr*. The *Goodlin* court denied preemptive effect to the concededly specific federal requirements, apparently because the FDA's Conditions of Approval were "not promulgated * * * with respect to [a] 'particular device.'" *Ibid.* Yet, so long as the specific federal requirement is applicable to a given device, *Lohr* does not demand that the requirement be applicable *exclusively* to that device. In fact, the FDA has frequently held that federal requirements have preemptive effect even though they apply to a wide array of devices. See, *e.g.*, Final Rule, *Medical Devices*, 45 Fed. Reg. 67,321, 67,322 (Oct. 10, 1980).

*Weiland*, in contrast, found that no aspect of the PMA process is specific. See 721 N.E.2d at 1152. It based that conclusion on two false premises, however: First, the court held that "[p]remarket approval imposes no ascertainable substantive requirement on the manufacture or design of the

device" (*ibid.*)—a statement that is untrue both in general (see 21 C.F.R. § 814.80 (prohibiting the manufacturer from making any change without FDA authorization to a device that has been approved by the agency through the PMA process if such change would affect the device's safety or effectiveness)) and in this case, where the FDA specifically approved the design, manufacturing process, and labeling of the Evergreen Balloon Catheter (see pages 5–7, *supra*). Second, the court held that the PMA process allows the FDA to assure only "the *minimal* safety of medical devices" (*id.* at 1153 (emphasis added)), a holding inconsistent with *Lohr*, which understood the "reasonable assurance" of safety and effectiveness to be a significant hurdle. *Lohr*, 518 U.S. at 477. In light of *Buckman*'s repetition of the significance of PMA review, see 531 U.S. at 343, the *Weiland* decision is plainly incorrect.[6]

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[6] Petitioners' attempt to conflate the investigational device exemption (IDE) process with the PMA process (see Pet. 16 n.4), in an effort to expand the scope of any conflict, should be rejected. Both of the decisions petitioners cite in footnote 4 are IDE rather than PMA cases and both specifically discuss differences between the PMA process and the IDE process. See *Connelly* v. *Iolab Corp.*, 927 S.W.2d 848, 850 (Mo. 1996) (en banc); *Niehoff* v. *Surgidev Corp.*, 950 S.W.2d 816, 818 (Ky. 1997). As the *Niehoff* court explained, the IDE process is designed "to encourage research and development" (950 S.W.2d at 818), whereas the PMA process includes "a determination that the product is safe and effective" (*ibid.*). Even were a state requirement not to be preempted based on the IDE process, then, the FDA's careful determination at the PMA stage that a product is safe and effective in light of all known risks should still preempt conflicting state requirements, including requirements imposed through common law tort actions. See *Lohr*, 518 U.S. at 501 ("The generality of [requirements imposed under the 510(k) process] make this quite unlike a case in which the Federal Government *has weighed the competing interests relevant to the particular requirement in question*, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers.") (emphasis added).

In the seven years since they were decided, no other court of appeals and no other state supreme court has joined either the Eleventh Circuit's decision in *Goodlin* or the Illinois Supreme Court's decision in *Weiland*. Given their internal flaws, this Court's reminder that the PMA process subjects a device to "thorough review," *Buckman*, 531 U.S. at 344, and the FDA's recent declaration that "through the PMA approval process [the FDA] certainly establishes 'specific requirements' applicable to a 'particular device,'" Brief for United States as *Amicus Curiae* (*Horn Amicus* Br.), 2004 WL 1143720, at *16, filed in *Horn* v. *Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) (see also pages 19–22, *infra*), there is no reason to believe that any court will repeat the errors in *Goodlin* or *Weiland*.

2. On the "state" side of the *Lohr* preemption equation, petitioners assert (Pet. 16) that there is a "profound" split of authority over whether state law damages claims can ever be preempted by divergent federal requirements. In fact, the vast majority of lower courts, and *all* courts to have considered the issue recently, have held that such claims can be preempted,[7] a decision that is plainly correct under *Lohr* (see pages 26–28, *infra*). Only one federal court of appeals or state court of last resort, cf. S. Ct. R. 10, has relied on a contrary finding to limit the preemptive scope of the MDA—the Tenth Circuit in *Oja* v. *Howmedica, Inc.*, 111 F.3d 782, 789 (10th Cir. 1997).[8] *Oja* is one of the earliest appellate deci-

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[7] See, *e.g.*, Pet. App. 30a; *McMullen*, 421 F.3d at 487; *Cupek*, 405 F.3d at 424; *Horn*, 376 F.3d at 173–177; *Brooks*, 273 F.3d at 799; *Martin*, 254 F.3d at 584; *Kemp*, 231 F.3d at 224; *Mitchell*, 126 F.3d at 913–914; *Papike* v. *Tambrands Inc.*, 107 F.3d 737, 741 (9th Cir. 1997); *Worthy*, 967 S.W.2d at 376–377; *Fry*, 695 A.2d at 517; *Green*, 685 A.2d at 117–118.

[8] Neither *Niehoff* nor *State ex rel. Miller* v. *New Womyn, Inc.*, 679 N.W.2d 593 (Iowa 2004), the only state supreme court decisions cited by petitioners (Pet. 17), holds that state common law claims are not subject to preemption when a medical device has received FDA approval through the PMA process. Petitioners' parenthetical quotation suggesting that the

sions to interpret *Lohr*, did not involve a device that had been approved through the PMA process, and plainly misinterprets *Lohr* in a variety of ways.

For example, the Tenth Circuit never directly considered whether a finding of liability under a state common law duty would "have the effect of establishing a substantive requirement of a specific device"—even though the court earlier had acknowledged that such an inquiry was necessary. 111 F.3d at 788 (quoting *Lohr*, 518 U.S. at 500 (in turn quoting 21 C.F.R. § 808.1(d)(1)) (internal quotation marks omitted). More importantly, the court failed to appreciate that a majority of this Court had expressly held in *Lohr* that state common law damages actions impose "requirements" that can be preempted by federal requirements. See pages 26–27 & n.15, *infra*.[9]

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Supreme Court of Kentucky, in *Niehoff*, held that state law damages claims are not specific requirements is taken out of context and misread. Rather, the *Niehoff* court held that the IDE process (not the PMA process) imposes no specific *federal* requirement against which to compare Kentucky's common law damages claims. See 950 S.W.2d at 822 ("[t]he claim * * * of preemption to the defective design allegation fails because there is no specific federal requirement"). As discussed above (at page 15 n.6), the *Niehoff* court also focused on the significant differences between the PMA process and the IDE process. In *New Womyn*, a case brought by the state attorney general under the state's consumer fraud statute, the device at issue had not been approved by the FDA at all, let alone after "running the gauntlet of the PMA process." *Lohr*, 518 U.S. at 494. Indeed, an FDA "employee with extensive experience in the review of applications regarding new medical devices" testified that a device similar to that at issue in *New Womyn* "was on display in the public lobby of the FDA building in a collection of what the FDA labeled 'quack devices.'" *New Womyn*, 679 N.W.2d at 597. Thus, even if the Supreme Court of Iowa had discussed whether a state law damages claim could in theory be preempted (which it did not), there was no specific federal requirement in *New Womyn* to preempt any state law claim.

[9] The *Oja* court was confused not only about what state requirements may be preempted but also about what federal requirements are preemptive. Thus, though the court was confronted with a claim (for failure to

This single aberrant decision by a federal court of appeals, rendered shortly after *Lohr*, does not warrant this Court's attention. In the nine years since *Oja*, there has been no movement by any other court toward that court's erroneous analysis. Moreover, given this Court's holding in *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 443 (2005), that the term "requirements" in the identically-worded FIFRA includes common law claims, the unanimous view of the other courts of appeals that such claims may be preempted, and the United States' similar view as expressed in its *amicus* brief in *Horn* (see pages 21–23, *infra*), there is no reason to believe that the Tenth Circuit would continue to follow *Oja* after further analysis of this Court's holding in *Lohr*.

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Petitioners, who suggest that review is warranted in this case because *Goodlin*, *Weiland*, and *Oja* "remain the law in those jurisdictions," summarily dismiss the prospect that "the courts that found no preemption might change their minds or be overturned en banc." Pet. 2–3. Petitioners' pessimism, however, is unwarranted. The issue of preemption in the PMA context arises relatively infrequently.[10] Thus, the courts

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warn) arising from a device approved, at the time it was implanted, only through the 510(k) process (see 111 F.3d at 787 n.2), it held that the FDA's 510(k) review led to specific federal requirements—despite this Court's contrary holding in *Lohr*. See 111 F.3d at 789.

[10] As the Second Circuit noted below, last year "approximately ninety-nine percent of [Class III] devices went through the § 510(k) process and only *one percent* went through the PMA process." Pet. App. 13a (emphasis in original). See also *Lohr*, 518 U.S. at 479 ("the § 510(k) premarket notification process became the means by which most new medical devices—including Class III devices—were approved for the market"). Because "the vast majority of Class III medical devices" enter the market via the § 510(k) process (Pet. App. 12a), and because the § 510(k) process is in essence a grandfathering provision that allows devices "substantially equivalent" to pre-MDA devices to enter the market without PMA approval (*ibid.*), it is not surprising that PMA-based preemption claims did not arise immediately after passage of the MDA. The first opportunity to assert preemption based on PMA approval would not have arisen until

that issued those early, anomalous decisions have had no opportunity to revisit their holdings.[11] Given the fact that no federal court of appeals and no state supreme court has followed—and, indeed, each such court has specifically *rejected*—those decisions in the years since they were issued, it is highly unlikely that they will be reaffirmed when the opportunity arises. On the contrary, given this Court's subsequent guidance in *Geier*, *Buckman*, and *Bates*, and the FDA's authoritative declaration in *Horn*, any vestigial conflict that still exists will almost certainly disappear without intervention by this Court.

### B. The lower courts should be allowed to consider the implications of the FDA's *amicus* brief in *Horn*.

In *Lohr*, this Court recognized that "Congress has given the FDA a unique role in determining the scope of § 360k's pre-emptive effect." 518 U.S. at 495–496. The Court further recognized that, as the federal agency to which Congress has delegated the authority to implement the MDA, the FDA "is uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress,'

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after a device had both "run[] the gauntlet of the PMA process," 518 U.S. at 494—a process that may take many years, see, *e.g.*, *Kemp*, 231 F.3d at 219 (regulatory review culminating in PMA approval lasted eight years)—*and* had allegedly caused injury to a patient. Therefore, contrary to petitioners' suggestion (Pet. 23), the fact that no court addressed PMA-based preemption in the years immediately following enactment of the MDA in no way undermines the fact that § 360k(a) clearly preempts state law claims that would impose requirements "different from" or "in addition to" the federal requirements embodied in the FDA's pre-market approval of their devices.

[11] A thorough review of the Westlaw Keycite database performed on October 3, 2006, reveals that no Tenth Circuit case citing *Oja*, no Eleventh Circuit case citing *Goodlin*, and no Illinois Supreme Court (or even appellate court) case citing *Weiland* has concerned common law damages claims in connection with a PMA-approved device.

and, therefore, whether it should be pre-empted." *Id.* at 496 (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)). Given "the ambiguity in the statute" and "the congressional grant of authority to the agency on the matter contained within it," the Court found it appropriate to "giv[e] substantial weight to the agency's view of the statute." *Ibid.*

The FDA has recently provided authoritative guidance on the scope of § 360k's preemptive effect in the PMA context. At the request of the Third Circuit, the United States submitted an *amicus* brief on behalf of the FDA in *Horn* v. *Thoratec Corp.*, 376 F.3d 163 (2004). The FDA's *amicus* brief explains at length and in detail why "FDA pre-market approval for a new medical device preempts state law tort judgments." *Horn Amicus* Br., 2004 WL 1143720, at *2.

With respect to the federal side of the equation, the FDA stated unequivocally that "through the PMA approval process [the FDA] certainly establishes 'specific requirements' applicable to a 'particular device.'" *Id.* at *16. The FDA noted that "[a]lthough the PMA approval order does not itself expressly reiterate all of the specific features the device's design, labeling, and manufacturing processes must have, it specifically approves as a matter of federal law those features as set forth in the application and binds the manufacturer to produce and market the product in compliance with the specifications as approved by [the] FDA." *Id.* at *24.

With respect to the state side of the preemption equation, the FDA endorsed the view—subscribed to by a majority of the Justices in *Lohr*—that "state tort law judgments do impose a requirement for purposes of preemption under the MDA when a common law action 'would impose a requirement different from, or in addition to, that applicable under the FDCA.'" *Id.* at *18 (quoting *Lohr*, 518 U.S. at 511 (O'Connor, J., concurring in part and dissenting in part)). The FDA observed that, absent an allegation that the device in question deviated from the requirements imposed by the FDA through the PMA process, "any finding of liability

* * * would necessarily rest upon an implicit requirement that [the] device be designed, manufactured, or marketed in a way that differs from the way approved by [the] FDA." *Ibid.*

The FDA also emphasized in its brief the "very strong public policy considerations" that support finding PMA approval preemptive of state common law claims. *Id.* at *25. According to the FDA—the agency charged with implementing the MDA—"[s]tate common law tort actions threaten the statutory framework for the regulation of medical devices." *Ibid.* As the agency explained, during the PMA process it conducts "a thorough review of a substantial scientific record" (*id.* at *16) and performs a "careful balancing" of the benefits and risks associated with a particular device (*id.* at *29). State tort actions, however, usurp "the central role of [the] FDA" by requiring "lay judges and juries to second-guess the balancing of benefits and risks of a specific device." *Id.* at *25. Because such second-guessing "may disrupt the careful balancing performed by the FDA in the PMA process" (*id.* at *29), state common law claims such as those asserted in *Horn*—and here—"are preempted under federal law." *Id.* at *31.

Given the agency's "unique role in determining the scope of § 360k's pre-emptive effect" (*Lohr*, 518 U.S. at 495–496), the FDA's clear guidance in *Horn* further demonstrates that there is no need for this Court to grant review in this case. The FDA's "reasoned analysis" (*Horn Amicus* Br., 2004 WL 1143720, at *30) is entitled to substantial weight as "the agency's fair and considered judgment on the matter in question." *Auer* v. *Robbins*, 519 U.S. 452, 462 (1997) (deferring to agency interpretation of ambiguous regulation contained in *amicus* brief submitted in dispute between private parties). This is especially true when coupled with this Court's renewed recognition of "the PMA review's rigor" (*Buckman*, 531 U.S. at 348), and Justice Stevens' reminder that "in *Medtronic, Inc.* v. *Lohr*, [this Court] recognized that the statutory reference to 'any requirement' imposed by a

State * * * may include common-law duties" (*Geier*, 529 U.S. at 897 (Stevens, J., dissenting); see also n.15, *infra*).

There is simply no reason to believe that those few courts that misinterpreted *Lohr* soon after it was decided will not now take heed of the FDA's *amicus* brief in *Horn* and join the clear consensus finding state common law claims that would impose requirements that are "different from" or "in addition to" the federal requirements embodied in the FDA's pre-market approval of a device to be preempted by federal law.[12] In the unlikely event that those courts, upon reconsideration, choose to adhere to their prior decisions, the Court can grant review at that time.

## II. The Decision Below, Finding Preemption Of State Law Claims Based On The Requirements Imposed By The PMA Process, Is Plainly Correct.

Review is also unwarranted because the decision below is consistent with *Lohr*, with Congress's intent in passing the MDA, with the views of the FDA, and with common sense. Section 360k(a) prohibits any state "requirement" that is "different from, or in addition to, any requirement applicable under [the MDA] to the device" and "which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the MDA]." Thus, for preemption to occur, there must be a federal re-

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[12] Notably, each circuit to have considered the question since the filing of the FDA's *amicus* brief in *Horn* has embraced the government's view that PMA approval preempts state common-law claims that would impose requirements "different from, or in addition to" the requirements imposed through the PMA process. See, *e.g.*, Pet. App. 37a–38a; *Horn*, 376 F.3d at 177. Petitioners do not cite, and respondent is not aware of, any district court or state court decision to arrive at a contrary conclusion since the filing of the FDA's *amicus* brief in *Horn*. Cf. *Hughes* v. *Cook*, No. 2:06-CV-02027, slip op. at 13 (W.D. Tenn. Sept. 27, 2006) (holding state common-law claims to be preempted by PMA approval based on *Kemp*, which, the court explained, "is heavily reenforced by the FDA's *amicus curiae* brief submitted in *Horn*").

quirement, a state requirement, and some "differen[ce]" between the two. See 518 U.S. at 500. These criteria are easily satisfied here.

1. The Second Circuit correctly held that FDA approval of a medical device through the PMA process can create federal requirements applicable to the device that would preempt conflicting state requirements. Although the Court in *Lohr* did not directly reach that question, both the majority and the dissenting opinions are fully consistent with a finding that the PMA process can impose preemptive federal requirements. See 518 U.S. at 501 (discussing preemption where "the Federal Government has weighed the competing interests relevant to the particular requirement in question," in contrast to the 510(k) process); *id.* at 512 (O'Connor, J., concurring in part and dissenting in part) (disputing requirement that federal requirements need to be specific). Moreover, the decision below is entirely consistent with the views of the FDA, which has declared that the PMA process "establishes 'specific requirements' applicable to a 'particular device.'" *Horn Amicus* Br., 2004 WL 1143720, at *16.[13]

It is clear that the PMA process in fact established specific requirements applicable in particular to the Evergreen Balloon Catheter. During that process, Medtronic submitted "test data, the results of clinical investigations and design information" as well as details of the device's manufacturing

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[13] The FDA's view is well supported by statute. Many provisions of the MDA refer to "requirements" imposed by the FDA through the PMA process (pursuant to 21 U.S.C. § 360e). See 21 U.S.C. §§ 331(e), 351(f)(1)(A)(i), 360(k)(2), 360c(b)(1)(A), 360c(c)(2)(A), 360c(e)(1)(B), 360e(b), 360e(c)(2), 360e(d)(2)(C), 360e(f), 360j(a), 360j(m)(2), 382(a)(2)(A). Under federal law, moreover, a device that is approved for marketing through the PMA process cannot be "manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device." 21 C.F.R. § 814.80; see also *id.* § 814.39. Put differently, the manufacturer is *required* to follow the design and other specifications embodied in the PMA application and approved by the FDA.

process and "full copies of proposed product labels." Pet. App. 65a–67a. After a "rigorous review" of this information, all of which "was specific to the Evergreen Balloon Catheter," the FDA "explicitly approved" the device's design, manufacturing method, and labeling. Pet. App. 28a, 65a–67a. Because Medtronic was thereafter prohibited from making any changes that might affect the safety or efficacy of the Evergreen Balloon Catheter, "the device is clearly subject to the federal, device-specific requirement of adhering to the standards contained in its individual, federally approved PMA." Pet. App. 26a. See also *Kemp*, 231 F.3d at 226–227 ("'PMA approval by the FDA constitutes approval of the product's design, testing, intended use, manufacturing methods, performance standards and labeling' and is 'specific to the product.'") (quoting *Mitchell*, 126 F.3d at 913).[14]

Significantly, approval through the PMA process entailed a finding, based on the FDA's painstaking review of an immense amount of scientific data, that "the device is both

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[14] Petitioners assert (Pet. 20) that "the PMA process itself does not impose specific federal 'requirements' * * * because the device's specifications originate with the manufacturer, not the FDA." Petitioners are wrong. Once the PMA application has been approved, often after prolonged discussions and agency-directed modifications, the device's manufacturer is legally obligated to adhere to the specifications set forth in the application and may not change them without FDA approval. See 21 C.F.R. § 814.80; see also *Horn*, 376 F.3d at 171–172. Moreover, the case that petitioners cite, *American Airlines, Inc.* v. *Wolens*, 513 U.S. 219, 228–229 (1995), does not suggest otherwise. In that case, this Court held that the Airline Deregulation Act preempted certain claims but did not preempt a breach of contract claim based on the defendant's "self-imposed undertakings." In so holding, however, the Court specifically noted that the defendant's contractual duties were "privately ordered obligations"; furthermore, there was no dispute that the defendant in that case could have unilaterally revised its self-imposed duties on a prospective basis without obtaining regulatory approval. *Id.* Here, by contrast, Medtronic could not—either unilaterally or in agreement with petitioners—alter its obligations after receiving PMA approval without first obtaining the FDA's consent.

safe and effective." *Lohr*, 518 U.S. at 477 (citing 21 U.S.C. § 360e(d)(2)). See also Pet. App. 25a ("'PMA approval is based on a determination by FDA that the PMA contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s).'"); *Horn Amicus* Br., 2004 WL 1143720, at *16 ("The approval perforce embodies the agency's conclusion that there is a 'reasonable assurance of safety and effectiveness' of the device."). The determination that a product is safe and effective, made after weighing "any probable benefit to health from the use of the device against any probable risk of injury or illness from such use" (21 U.S.C. § 360c(a)(2)(C))—in a process characterized by this Court as "running the gauntlet" (*Lohr*, 518 U.S. at 494) and "exhaustive" (*Buckman*, 531 U.S. at 349)—is of necessity the determination that the attributes of that device are an appropriate compromise that should not be modified by state law. See *Horn Amicus* Br., 2004 WL 1143720, at *29 ("state co-regulation" through tort actions "may disrupt the careful balancing performed by [the] FDA in the PMA process").

The regulatory history confirms this point. Petitioners rely on 21 C.F.R. § 808.1(d), cf. Pet. 15, but—as evidenced by the FDA's *amicus* brief in *Horn*—that regulation is entirely consistent with holding that the PMA process establishes device-specific requirements. Section 808.1(d) explains that state or local requirements will be preempted when the FDA "has established specific counterpart regulations *or there are other specific requirements applicable to a particular device under the [MDA]*." (emphasis added). The preamble to section 808.1(d) notes that a state cannot, through its own premarket approval process, establish requirements inconsistent with the FDA's premarket approval process, and further explains:

> For a device classified in class III under section 513(d) of the act, the counterpart FDA requirement is established on the date the device can not lawfully

> be marketed without application for premarket approval. * * * Once these FDA requirements are established, different or additional State requirements are preempted.

Final Rule, *Exemptions From Federal Preemption of State and Local Device Requirements: Procedures For Consideration of Applications*, 43 Fed. Reg. 18,661, 18,664 (May 2, 1978) (emphasis added).

Finally, Congress viewed the PMA process as imposing "requirements" that would trigger preemption. For example, prior to passage of the MDA, California's "Sherman Food, Drug, and Cosmetic Law" required pre-market approval of all new devices sold in the state. Congress specifically referred to this requirement as one that the FDA should allow to continue by expressly exempting it (under 21 U.S.C. § 360k(b)) from preemption by the PMA process. See H.R. REP. NO. 94-853, at 45–46. No such exemption would have been thought necessary if the PMA process did not establish requirements otherwise preemptive of the state law.

2. The Second Circuit also correctly found that petitioners' state law claims, to the extent those claims were based on a showing that the device should have been manufactured, designed, or labeled in a manner different from that required by the PMA, were preempted under § 360k. A majority of this Court held in *Lohr* that "the MDA will sometimes preempt a state-law tort suit" (518 U.S. at 503 (Breyer, J., concurring)), because "insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action" (*id.* at 504–505); accord *id.* at 509 ("state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the FDCA.") (O'Connor, J., concurring in part and dissenting in

part).[15] When a state law tort action is based on a requirement that is not identical to a federal requirement, that claim would seem definitionally to be "different from, or in addition to" (21 U.S.C. § 360k(a)(1)) the federal requirement. Indeed, as noted by the FDA, "any finding of liability * * * would necessarily rest upon an implicit requirement that [the] device be designed, manufactured, or marketed in a way that differs from the way approved by [the] FDA." *Horn Amicus* Br., 2004 WL 1143720, at *18.

Here, the PMA process imposed specific requirements on Medtronic, including the requirement to label the Evergreen Balloon Catheter in precisely the manner approved in its PMA application, with, for example, warnings that the device not be used in patients with calcified stenoses and not be inflated to more than the Rated Burst Pressure. See pages 7–8, *supra*. The district court found that petitioners had prof-

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[15] Indeed, contrary to what petitioners suggest (Pet. 20–21), *all* members of the *Lohr* Court agreed that state common-law claims could potentially be preempted under the MDA. Thus, in Section V of the *Lohr* decision, the Court, referring to § 360k(a) and 21 C.F.R. 808.1(d), observed that "we do not believe that this statutory and regulatory language necessarily precludes . . . 'general' state requirements from ever being preempted." 518 U.S. at 500. Significantly, Justice Stevens, who wrote the opinion in *Lohr*, has himself stated that *Lohr* "recognized that the statutory reference to 'any requirement' imposed by a State * * * may include common-law duties." *Geier*, 529 U.S. at 897 (Stevens, J., dissenting). See also *Geier*, 529 U.S. at 867 (noting that "a majority of this Court" in *Lohr* recognized that state tort actions may be preempted as imposing conflicting "requirements"); cf. *Bates*, 544 U.S. at 443 ("the term 'requirements' * * * reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties"). Because the entire *Lohr* Court agreed that state common-law claims could, at least potentially, be preempted, the fact that Justice Breyer's articulation of this proposition is contained in a concurrence is beside the point. Cf. Pet. 21. The *Lohr* Court was not divided over the question *whether* state common-law claims might be preempted; the Justices disagreed only over the *frequency* with which they would be preempted. See 518 U.S. at 502–503 (Stevens, J., plurality); *id.* at 508 (Breyer, J., concurring); *id.* at 509 (O'Connor, J., dissenting).

fered no evidence suggesting that Medtronic had deviated from the requirements imposed by the FDA through the PMA process. Pet. App. 90a. Thus, were a jury to impose liability on Medtronic under state law, that jury would of necessity be imposing a requirement "different from" or "in addition to" that imposed by the FDA under federal law.

3. Putting aside the legalisms of *Lohr*, petitioners' position cannot possibly be consistent with Congress's decision to enact the MDA and to make that statute preemptive. The MDA strikes a careful balance between shielding the public "against unsafe, unproven, ineffective, and experimental medical devices" and ensuring that progress in the development of medical devices is not "stifle[d]" by "excessive or ill-conceived" regulation. H.R. REP. NO. 94-853, at 10; see also *FDA Oversight: Medical Devices: Hrg. Before the Subcomm. on Oversight & Investigations of House Comm. on Energy & Commerce*, 97th Cong., 2d Sess. 5 (1982). A key element in striking this balance is Congress's delegation of exclusive authority to the FDA. Permitting state review and nullification of the FDA's PMA decisions would run roughshod over this carefully calibrated enforcement scheme and would impose the "undu[e] burden[]" of differing state regulation that Congress aimed to avoid by including in the MDA a "general prohibition on non-Federal regulation." H.R. REP. NO. 94-853, at 45.

Moreover, petitioners raise a red herring when they assert that "the decision below leaves patients injured by the most risky devices with no remedy." Pet. 22. As the Second Circuit itself emphasized, the scope of its decision is "quite limited." Pet. App. 36a. First, it affects only those devices that the FDA deems safe and effective after rigorous PMA review; it does not apply to the vast majority of Class III devices, 99% of which enter the market via the less-exacting 510(k) process. Second, the decision "does not even hold that all state tort claims as to PMA-approved devices are preempted." *Ibid.*

> On the contrary, * * * tort claims that are premised on a manufacturer's deviation from the standards set forth in the device's approved PMA application—such as the Riegel's negligent manufacturing claim—are in no way preempted. Only those claims that allege liability despite a PMA-approved device's adherence to those standards are, pursuant to this decision, preempted. As one article recently noted, "[t]his is a relatively small universe of cases."

*Ibid.* (quoting Gregory J. Scandaglia & Therese L. Tully, *Express Preemption and Premarket Approval Under the Medical Device Amendments*, 59 FOOD DRUG L.J. 245, 263–264 (2004)). See also *Lohr*, 518 U.S. at 495 ("Nothing in § 360k denies [a state] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements."); *Mitchell*, 126 F.3d at 914 ("to the degree that these claims may be read to allege that [the device manufacturer] failed to meet the standards set forth in the PMA process, the allegations are not preempted"). Thus, contrary to petitioners' assertion, patients remain fully protected, both by the FDA's rigorous scrutiny of PMA-approved devices and by the ability to enforce FDA-imposed requirements through common law claims.

* * * * *

In the final analysis, petitioners present this Court little evidence of a significant split in authority below; what inconsistencies there may be in the interpretation of *Lohr* are likely to be resolved in light of the FDA's *amicus* brief in *Horn* and through further litigation in the lower courts. Petitioners provide no good reason why the Court, having repeatedly declined to review this issue, should grant review here, or why the issue deserves the Court's attention at the present time.

## CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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IN THE
# Supreme Court of the United States

CHARLES R. RIEGEL and DONNA S. RIEGEL,
*Petitioners,*

v.

MEDTRONIC, INC.,
*Respondent.*

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Second Circuit

## REPLY BRIEF FOR PETITIONERS

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## TABLE OF AUTHORITIES

CASES Pages

*Bates v. Dow AgroSciences*,
544 U.S. 431 (2005) ..... 3, 4

*Bowling v. Pfizer*,
143 F.R.D. 141 (S.D. Ohio 1992) ..... 6

*Buckman Co. v. Plaintiffs' Legal Committee*,
531 U.S. 341 (2001) ..... 4, 5

*Geier v. American Honda Motor Co.*,
529 U.S. 861 (2000) ..... 4, 5

*Goodlin v. Medtronic*,
167 F.3d 1367 (11th Cir. 1999) ..... 1, 6, 7

*Guidant Corp. Implantable Defibrillators Products Liability Litigation*, 398 F.Supp.2d 1371
(D. Minn. 2005) ..... 6

*Horn v. Thoratec*,
376 F.3d 163 (3d Cir. 2004) ..... 3, 10

*Jimenez v. Medtronic*,
No. 05-1088 (M.D. Fla. Oct. 18, 2005) ..... 1

*Kemp v. Medtronic*,
231 F.3d 216 (6th Cir. 2000) ..... 6

*Leslie v. Cincinnati Sub-Zero Products, Inc.*,
961 S.W.2d 799 (Ky. App. 1998) ..... 9

*Martin v. Medtronic*,
254 F.3d 573 (5th Cir. 2001) ..... 6

*Medtronic v. Lohr*,
518 U.S. 470 (1996) ..... 1

*Mitchell v. Collagen Corp.*,
126 F.3d 902 (7th Cir. 1997) ..... 2, 10

*Niehoff v. Surgidev*,
950 S.W.2d 816 (Ky. 1997) ..... 9

*Oja v. Howmedica*,
111 F.3d 782 (10th Cir. 1997) ..... 8, 9

*Smith Industries Medical System v. Kernats*,
675 N.E.2d 634 (Ill. 1996) ..... 2

*State ex rel. Miller v. New Womyn, Inc.*,
679 N.W.2d 593 (Iowa 2004) ..... 10

*In re: Sulzer Hip Prosthesis and Knee Prosthesis Liability Litigation*, 268 F. Supp. 2d 907
(S.D. Ohio 2003) ..... 6

*Weiland v. Telectronics Pacing Systems, Inc.*,
721 N.E.2d 1149 (Ill. 1999) ..... 2, 7, 8

*Worthy v. Collagen Corp.*,
967 S.W.2d 360 (Tex. 1998) ..... 2

STATUTES AND REGULATIONS

21 U.S.C. § 360c(a)(C) ..... 6

21 U.S.C. § 360k(a) ..... 1

21 C.F.R. § 801.109 ..... 7

21 C.F.R. § 807.81(a)(3) ..... 7

21 C.F.R. § 808.1 ..... 3, 8

21 C.F.R. § 808.1(d)(1) ..... 10

21 C.F.R. § 814.80 ..... 7

## REPLY BRIEF FOR PETITIONERS

The parties agree on two points. First, the lower courts are in conflict over the question whether 21 U.S.C. § 360k(a) preempts medical devices marketed under the FDA's premarket approval ("PMA") process. Second, this question has been presented in prior petitions filed in this Court, which the Court has denied. These points of agreement are related because, in response to the prior petitions, respondent has argued that the conflict would disappear without this Court's assistance.[1] Yet today, nearly a decade after the conflict arose, it remains in place on both the federal and state sides of the preemption analysis outlined by the Court in *Medtronic v. Lohr*, 518 U.S. 470 (1996).

1. Medtronic says that its inability to find recent damages cases involving PMA devices and addressing preemption in some of the jurisdictions that have held that section 360k(a) does not preempt damages claims suggests that those holdings are not strong precedent in those jurisdictions. Opp. 19 & n.11. Logically, it means the opposite. That the Eleventh Circuit has not had cause to revisit *Goodlin v. Medtronic*, 167 F.3d 1367 (11th Cir. 1999), for example, means not that *Goodlin* was "anomalous," Opp. 19, but that it is respected as the law of the Circuit. In fact, in a district court case in Florida, Medtronic made arguments similar to those it makes here—that *Goodlin* need not be followed because some other courts disagreed with its holding and because the FDA had since reversed its view to favor preemption. The Court responded: "Not only does the court 'feel bound' by the *Goodlin* decision, it *is* bound by the decision . . . ." *Jimenez v. Medtronic*, No. 05-1088 (M.D. Fla. Oct. 18, 2005) (order

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[1] *See* Br. for Resp. in *Knisley v. Medtronic*, No. 05-22 (filed Sept. 6, 2005), Br. for Resp. in *Martin v. Medtronic*, No. 01-441 (filed Nov. 14, 2001), and Br. for Resp. in *Kemp v. Medtronic*, No. 00-1766 (filed July 23, 2001).

denying motion for protective order). Likewise, the Illinois Supreme Court has twice had the opportunity to consider whether section 360k(a) preempts damages claims with respect to PMA devices, including once after several appellate courts had held that such claims are preempted. *See, e.g.*, *Mitchell v. Collagen Corp.*, 126 F.3d 902 (7th Cir. 1997); *Worthy v. Collagen Corp.*, 967 S.W.2d 360 (Tex. 1998). The Illinois court nonetheless held that section 360k(a) does not preempt damages claims. *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E. 1149 (Ill. 1999); *see also Smith Indus. Med. Sys. v. Kernats*, 675 N.E.2d 634 (Ill. 1996) (denying review of appellate court decision holding no preemption).

2. The question presented here is what the language of section 360k(a) means. In two briefs filed in this Court, the FDA has argued that the plain language of section 360k(a) does not preempt state-law damages claims, including claims arising from PMA devices. *See* Br. of U.S. as Amicus Curiae in *Smith Indus. Medical Sys. v. Kernats*, S. Ct. No. 96-1407, at 14-18 (filed Dec. 1997) (regarding PMA device); Br. of U.S. as Amicus Curiae in *Medtronic v. Lohr*, S. Ct. No. 95-754, 1996 WL 118035 (filed Mar. 1996) (regarding § 510(k) device).

In 2004, the FDA reversed itself. In a Third Circuit amicus brief, the FDA acknowledged its prior position that section 360k(a) does not preempt damages claims but made an about-face to argue that section 360k(a) does preempt such claims. Br. of U.S. as Amicus Curiae in *Horn v. Thoratec*, 3d Cir. No. 02-4597, 2004 WL 1443720 (filed May 14, 2004).

Now, Medtronic suggests that the FDA's 2004 brief will cause the conflicts among the lower courts to disappear. This suggestion is unfounded. To begin with, the conflict existed before 2004, even in the face of an FDA brief clearly stating the agency's view that damages claims involving PMA devices were generally not preempted. *See* Br. of U.S. as Amicus

Curiae in *Smith Indus. Med. Sys.*, *supra* p. 2. The number of courts that, between 1997 and 2004, held that claims involving PMA devices are preempted shows that the lower courts simply do not give FDA amicus briefs on this question much weight.

Now that the FDA has reversed its position, its amicus briefs are entitled to even less consideration by the courts. As Judge Pooler noted below, an agency's claims that an express preemption provision extends to damages claims are "particularly dubious" where, until relatively recently, the regulating agency did not think that such claims are preempted. Pet. App. 46a (quoting *Bates v. Dow AgroSciences*, 544 U.S. 431, 449 (2005)).

Thus, not surprisingly, the FDA's 2004 brief has done nothing to minimize the undeniable disagreement about the scope of section 360k(a). Rather, although both federal courts of appeals to have considered the issue since the FDA filed its brief have found preemption, one court paid little attention to the FDA's brief, *see* Pet. App. 14a, 37a-38a, and both decisions provoked strong dissents. *See id.* 46a-47a (Pooler, J., dissenting); *Horn v. Thoratec*, 376 F.3d 163, 182 n.29 (3d Cir. 2004) (Fuentes, J., dissenting) (noting that arguments advanced in agency amicus briefs "are entitled to 'near indifference,' and are only as persuasive as their merits dictate") (quoting defendant).

Moreover, as the dissent noted in *Horn*, "the *Lohr* court gave deference to the FDA's regulations in particular, not to an amicus brief." *Id.* Because the relevant FDA regulation (21 C.F.R. § 808.1) has not changed in nearly 30 years and the FDA's 2004 brief did not tie its argument to that regulation, the FDA's amicus brief should not affect the views of the courts on either side of the conflict.

3. If there is a development that should affect the lower courts' approaches to interpreting the scope of section 360k(a),

it is not the seesawing views of the FDA; it is this Court's developing preemption jurisprudence. Over the past decade, the Court has consistently reversed lower court decisions broadly construing express preemption provisions to preempt damages claims. *See* Pet. 18 (citing cases). Most recently, the Court in *Bates* resolved a conflict far more lopsided than the one at issue here by rejecting a pesticide company's preemption argument based on a statutory provision "similarly worded" to section 360k(a). 544 U.S. at 447.

Many lower courts have failed to heed the Court's direction with respect to construction of express preemption provisions. Medtronic's brief in opposition reflects this same shortcoming. For example, Medtronic twice cites *Bates* for the proposition that a statutory provision that preempts "requirements" may encompass damages claims. Opp. 18 & 27 n.5 (citing *Bates*, 544 U.S. at 443); but Medtronic never acknowledges that *Bates rejected* the broad preemption holdings of nine federal courts of appeals. Much of what the Court stated in *Bates* with respect to claims against pesticide manufacturers is equally true here: "The long history of tort litigation against manufacturers . . . adds force to the basic presumption against pre-emption," 544 U.S. at 449, and "[w]e have been pointed to no evidence that such tort suits led to a 'crazy-quilt' of [federal] standards or otherwise created any real hardship for manufacturers or for [the agency]. Indeed, for much of this period [the agency] appears to have welcomed these tort suits." *Id.* at 451-52.

4. Unable to deny the conflict among the lower courts, Medtronic argues that the conflict may diminish in light of two implied preemption cases—*Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), and *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000). Medtronic's speculation has no basis, and, in any event, time has already proven it wrong.

First, Medtronic's focus on *Buckman* is a distraction, for that case does not address the question presented here. Accordingly, although four years have passed since the Court decided *Buckman*, the split in authority is as deep as ever.

That *Buckman* has not affected cases construing section 360k(a) is not surprising. In holding that a fraud-on-the-FDA claim is impliedly preempted, *Buckman* explicitly distinguished that claim from claims "relying on traditional state tort law which had predated the federal [medical device] enactments in question." 531 U.S. at 353. Moreover, *Buckman* involved neither a PMA device nor preemption under section 360k(a). *Buckman*'s only discussion of PMA appears in a description of the medical device regulatory scheme. *Id.* at 344. That description is taken wholly from FDA regulations and from *Lohr*, and thus has always been available to the courts on both sides of the post-*Lohr* conflict on which the petition is based. Aside from that background discussion, *Buckman* mentions PMA only in passing. *Id.* at 348, 349.

Second, Medtronic repeatedly suggests that the Court's 2000 decision in *Geier* will cause courts to reconsider decisions finding no preemption. *Geier* involved the National Highway Traffic Safety Act. The Court found no express preemption but held that the plaintiff's damages claims were impliedly preempted because they would frustrate the agency's objective with regard to a specific motor vehicle safety standard. 529 U.S. at 867, 874-75. *Geier* has had no effect on the development of case law involving preemption under section 360k(a). Perhaps for this reason, Medtronic never discusses *Geier*'s facts or holding or explains why it repeatedly refers to it.

5. Medtronic tries to minimize the importance of the question presented here by emphasizing that PMA devices comprise only one percent of the devices that enter the market. Opp. 28. Whatever the validity of that statistic, PMA is

required for life-sustaining devices and those that present the greatest risk of causing injury, 21 U.S.C. § 360c(a)(C), which not surprisingly tends to lead to a disproportionate number of injuries and lawsuits. The number of reported cases involving PMA devices, some of which are cited in the petition and opposition, speaks to the frequency of injuries and litigation attributable to PMA devices. Indeed, one of Medtronic's own PMA devices recently sparked so many cases as to warrant coordination in multidistrict litigation. *See In re Medtronic Implantable Defibrillators*, MDL No. 1726 (D. Minn.) (pending). Another Medtronic PMA device led to dozens of individual lawsuits and reported decisions from three different federal courts of appeals. *See Martin v. Medtronic*, 254 F.3d 573 (5th Cir. 2001); *Kemp v. Medtronic*, 231 F.3d 216 (6th Cir. 2000); *Goodlin*, 167 F.3d 1367. Of course, Medtronic is not the only medical device manufacturer to have marketed a device that caused injuries and deaths and that led to significant litigation. *See, e.g., Bowling v. Pfizer*, 143 F.R.D. 141 (S.D. Ohio 1992) (settlement of class action arising from injuries to approximately 55,000 patients implanted with defective PMA heart valve); *In re: Sulzer Hip Prosthesis and Knee Prosthesis Liab. Litig.*, 268 F. Supp. 2d 907, 912-13 (S.D. Ohio 2003) (more than 3,880 patients required extra surgeries due to two defective PMA devices; more than 1,300 lawsuits filed); *Guidant Corp. Implantable Defibrillators Prods. Liab. Litig.*, 398 F.Supp.2d 1371 (D. Minn. 2005) (order creating MDL for cases involving PMA cardiac devices).

Thus, the relative number of PMA devices as compared to section 510(k) devices says little if anything about the number of injuries caused by PMAs and the number of patients who will go without any means of redress if the decision below stands.

6. Attempting to minimize the disarray in the lower courts, Medtronic focuses on a few of the cases cited in the

petition and argues that the cases were wrongly decided. Medtronic's descriptions of these cases consistently mischaracterize the courts' analyses.

First, Medtronic misrepresents the reasoning of *Goodlin*, omitting key aspects of the opinion and selectively quoting from two pages of a 10-page analysis. Opp. 17. In *Goodlin*, as here, Medtronic relied on the rigor of PMA review. The Eleventh Circuit understood, however, that the PMA process does not result in any device-specific requirement, but only in a finding that the company has demonstrated reasonable assurance of a device's safety and effectiveness. 167 F.3d at 1375. The court explained that "while a PMA review is considerably more rigorous and detailed than the premarket review notification [section 510(k)] process at issue in [*Lohr*], it is, in fact, no more 'specific a requirement.'" *Id.* at 1376 (quoting *Sowell v. Bausch & Lomb, Inc.*, 656 N.Y.S.2d 16, 20 (N.Y. App. Div. 1997)).

Next, Medtronic turns to *Weiland v. Telectronics Pacing Systems*, 721 N.E.2d 1149, which also holds that PMA does not preempt damages claims. Citing 21 C.F.R. § 814.80, the generally applicable regulation prohibiting manufacturers from altering the manufacturing or labeling of a PMA device in ways inconsistent with the conditions of approval, Medtronic disputes *Weiland*'s statement that PMA imposes no substantive requirements on the design or manufacture of the device. Opp. 15. To begin with, the relevant FDA regulations regarding section 510(k) devices, which were at issue in *Lohr*, are very similar to the PMA regulation cited as an example by Medtronic. *See* 21 C.F.R. § 807.81(a)(3) (prohibiting significant design or manufacturing changes prior to new section 510(k) submission); *see also id.* § 801.109 (prescription device labeling regulations applicable to both PMA and section 510(k) devices). Nonetheless, *Lohr* held that section 510(k) regulation does not trigger section 360k(a).

Furthermore, in the portion of *Weiland* cited by Medtronic, Opp. 14-15, the court is simply explaining that the design of the device originated with the company, and that the FDA had the authority to impose specific design standards but had not done so. 721 N.E.2d at 1152-53. Although it is true that PMA imposes various requirements on a manufacturer, both *Lohr*, 518 U.S. at 500, and the relevant FDA regulation, 21 C.F.R. § 808.1, instruct courts to consider whether those requirements are device-specific and whether state-law damages claims are counterparts to specific requirements. Notably, Medtronic never undertakes that analysis. That is, Medtronic never identifies what requirement a state-law damages claim would impose on the company, much less how that requirement would be different from or in addition to a device-specific federal requirement imposed through PMA. *See also Bates*, 544 U.S. at 443 ("A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.").

Turning to cases that hold that state-law damages claims are too general to fall within the preemptive scope of section 360k(a), Medtronic ignores many of the state-court decisions cited in the petition and focuses almost exclusively on *Oja v. Howmedica*, 111 F.3d 782 (10th Cir. 1997). While conceding that *Oja* conflicts with the decision below, Medtronic faults *Oja* for "never directly consider[ing] whether a finding of liability under a state common law duty would 'have the effect of establishing a substantive requirement for a specific device.'" Opp. 17 (quoting *Oja*, 111 F.3d at 788 (quoting *Lohr*, 518 U.S. at 500)). In reality, the Tenth Circuit "directly considered" that possibility and expressly found that "Howmedica's general duty to warn users of potential dangers in this case does not have 'the effect of establishing a substantive requirement for a specific device.'" 111 F.3d at 789. Medtronic also criticizes *Oja* for purportedly failing to recognize that, in *Lohr*, five

members of this Court would have held that state-law damages claims can, in some circumstances, impose requirements preempted by section 360k(a). Opp. 17. But *Oja* is fully consistent with that approach. The opinion applies *Lohr* at every step, *see generally* 111 F.3d at 788-89, and holds that the common-law claims at issue were based on generally applicable duties that did not relate specifically to devices.[2]

Medtronic also argues with the petition's citation to *Niehoff v. Surgidev*, 950 S.W.2d 816, 822 (Ky. 1997), which held that, under *Lohr*, state laws of general applicability that apply to all products fall outside the preemptive scope of section 360k(a). Medtronic (at 15 n.6) responds that *Niehoff* involved an investigational device, not a PMA device. That statement is correct, as the petition itself states, *see* Pet. 16 n.4, but irrelevant. *Niehoff*'s holding that generally applicable state-law claims are not preempted concerns the state-law side of the section 360k(a) preemption analysis and, therefore, applies with equal force to claims involving all types of devices, including PMA devices. Medtronic's claim (at 16 n.8) that *Niehoff* did not so hold is belied by the decision itself, *see* 950 S.W.2d at 822, and by a subsequent decision of the Kentucky Court of Appeals, which reads *Niehoff* precisely as Petitioners do. *See Leslie v. Cincinnati Sub-Zero Prods., Inc.*, 961 S.W.2d 799, 802-03 (Ky. App. 1998).

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[2]Medtronic (at 17 n.9) also derides *Oja* for finding that a specific federal requirement applied to the section 510(k) device at issue there, given that *Lohr* found no device-specific requirements applicable to the Medtronic section 510(k) device in that case. However, *Oja* involved injury caused by a device for which the FDA had imposed a device-specific labeling requirement. 111 F.3d at 789. Medtronic misrepresents *Oja* by suggesting that the Tenth Circuit held that the section 510(k) process itself imposed that requirement.

Similarly, *State ex rel. Miller v. New Womyn, Inc.*, 679 N.W.2d 593, 596 (Iowa 2004), addressed preemption under section 360k(a) and the FDA's preemption regulation, 21 C.F.R. § 808.1(d)(1), and held that the state law at issue was not preempted because it was a law of general applicability. Medtronic (at 16 n.8) dismisses this case on the ground that it did not involve a PMA device or a damages claim. Again, the factual assertions are correct but irrelevant. The Iowa Supreme Court's reading of *Lohr* and the applicable FDA regulation conflicts with the decisions in damages cases involving PMA devices, such as *Mitchell*, 126 F.3d at 912, and *Horn*, 376 F.3d at 174-75, that hold that section 360k(a) can preempt state-law claims of general applicability.

7. In Petitioners' view, the decision below is inconsistent with the text and purpose of the Medical Device Amendments, FDA regulations, and *Lohr*. Medtronic disagrees. The petition and opposition reveal the parties' drastically different understandings of the law and the significance of PMA. If the Court grants the petition, there will be time enough to respond to Medtronic's merits arguments in detail. For present purposes, the depth of the parties' disagreement on the merits only mirrors the depth of the disagreement among the lower courts and underscores the need for review.

## CONCLUSION

The petition for a writ of certiorari should be granted.

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37

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No. 06-179

# In the Supreme Court of the United States

CHARLES R. RIEGEL AND
DONNA S. RIEGEL, PETITIONERS

*v.*

MEDTRONIC, INC.

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT*

## BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

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## QUESTION PRESENTED

Whether, under the express preemption provision in 21 U.S.C. 360k, the Food and Drug Administration's premarket approval of a medical device preempts state-law tort claims relating to the safety or efficacy of the device.

## TABLE OF CONTENTS

Page

Statement ..... 1
Discussion ..... 7
A. The decision of the court of appeals is correct ..... 8
B. The decision of the court of appeals does not warrant review ..... 18
Conclusion ..... 20

## TABLE OF AUTHORITIES

Cases:

*Bates* v. *Dow Agroscis. LLC*, 544 U.S. 431 (2005) ..... 12, 14, 15, 16, 19
*Brooks* v. *Howmedica, Inc.*:
535 U.S. 1056 (2002) ..... 20
273 F.3d 785 (8th Cir. 2001), cert. denied, 535 U.S. 1056 (2002) ..... 18
*Collagen Corp.* v. *Green*, 520 U.S. 1212 (1997) ..... 20
*Fry* v. *Allergan Med. Optics*:
522 U.S. [illegible] (1997) ..... 20
695 A.2d 511 (R.I.), cert. denied, 522 U.S. 952 (1997) ..... 18
*Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999) ..... 18
*Green* v. *Dolsky*:
520 U.S. 1168 (1997) ..... 20
685 A.2d 110 (Pa. 1996), cert denied, 520 U.S. 1168, and 520 U.S. 1212 (1997) ..... 18

Cases—Continued: Page

*Horn* v. *Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) ..... 17, 18

*Kemp* v. *Medtronics, Inc.*:

534 U.S. 818 (2001) ..... 20

231 F.3d 216 (6th Cir. 2000), cert. denied, 534 U.S. 818 (2001) ..... 18

*Knisley* v. *Medtronic, Inc.*: 126 S. Ct. 420 (2005) ..... 20

*Martin* v. *Medtronic, Inc.*:

534 U.S. 1078 (2002) ..... 20

234 F.3d 573), (5th Cir. 2001), cert. denied, 534 U.S. 1078 (2002) ..... 18

*McMullen* v. *Medtronic, Inc.*:

126 S. Ct. 1464 (2006) ..... 20

421 F.3d 482 (7th Cir. 2005), cert. denied, 126 S. Ct. 1464 (2006) ..... 18

*Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996) ..... *passim*

*Niehoff* v. *Surgidev Corp.*, 950 S.W.2d 816 (Ky. 1997), cert. denied, 523 U.S.C. 1005 (1998) ..... 19

*Oja* v. *Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997) ..... 19

*Smith Indus. Med. Sys., Inc.* v. *Kernats*, 522 U.S. 1044 (1998) ..... 16

*State ex rel. Miller* v. *New Womyn, Inc.*, 679 N.W.2d 592 (Iowa 2004) ..... 19

*Weiland* v. *Telectronics Pacing Sys.*, 721 N.E.2d 1149 (Ill. 1999) ..... 18

Cases—Continued: Page

*Worthy* v. *Collagen Corp.*:
524 U.S. 954 (1998) ..... 20
967 S.W.2d 360 (Tex.), cert. denied, 524 U.S. 954 (1998) ..... 18

Statutes and regulations:

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.* ..... 1
21 U.S.C. 331(a)-(c) ..... 14
21 U.S.C. 352(a) ..... 14
21 U.S.C. 352(j) ..... 14
21 U.S.C. 360(k) ..... 2
Medical Device Amendments, 21 U.S.C. 360c *et seq.* ..... 1
21 U.S.C. 360c(a)(1) ..... 2
21 U.S.C. 360c(a)(1)(C) ..... 2
21 U.S.C. 360c(a)(2) ..... 3
21 U.S.C. 360c(a)(2)(B) ..... 11
21 U.S.C. 360c(a)(2)(C) ..... 11
21 U.S.C. 360e(a)(1) (2000 & Supp. IV 2004) ..... 2
21 U.S.C. 360e(b)(1)(A) ..... 2
21 U.S.C. 360e(c)(1) ..... 2
21 U.S.C. 360e(d)(1)(A) ..... 3, 11, 16
21 U.S.C. 360e(d)(1)(B) ..... 3
21 U.S.C. 360e(d)(2)(A) ..... 3

Statutes and regulations—Continued: Page

21 U.S.C. 360e(d)(2)(A)-(E) ..... 11
21 U.S.C. 360e(d)(2)(B) ..... 3
21 U.S.C. 360e(d)(2)(D) ..... 3
21 U.S.C. 360e(d)(6) ..... 3
21 U.S.C. 360e(e)(1)(A) ..... 12
21 U.S.C. 360e(e)(1)(B) ..... 12
21 U.S.C. 360e(e)(1)(F) ..... 12
21 U.S.C. 360j(e)(1) ..... 3
21 U.S.C. 360k ..... 8, 17, 19
21 U.S.C. 360k(a) ..... 4, 12, 15, 16, 19
21 U.S.C. 360k(a)(1) ..... 5, 11, 13
21 U.S.C. 360k(a)(2) ..... 13
21 U.S.C. 360k(b) ..... 4, 16
Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136v(b) ..... 14
21 C.F.R.:
Section 14.171 ..... 2
Section 814.20 ..... 2
Section 814.20(b)(13) ..... 2
Section 814.39 ..... 3
Section 814.39(d) ..... 3
Section 814.39(d)(1) ..... 3
Section 814.39(d)(2) ..... 3
Section 814.44(d)(1) ..... 3
Section 814.45(c) ..... 2
Section 814.80 ..... 3
Section 814.82 ..... 3

Miscellaneous: Page

62 Fed. Reg. (1997):
p. 65,384 ..... 17
p. 65,387 ..... 17
63 Fed. Reg. 39,789 (1998) ..... 17
71 Fed. Reg. 3935 (2006) ..... 17

# In the Supreme Court of the United States

No. 06-179

CHARLES R. RIEGEL AND
DONNA S. RIEGEL, PETITIONERS

*v.*

MEDTRONIC, INC.

*ON PETITION FOR A WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT*

## BRIEF FOR THE UNITED STATES AS AMICUS CURIAE

This brief is filed in response to the Court's order inviting the Solicitor General to file a brief expressing the views of the United States. In the view of the United States, the decision of the court of appeals is correct and does not warrant review by this Court.

## STATEMENT

1. This case presents the question whether premarket approval of a Class III medical device by the Food and Drug Administration (FDA) preempts state-law tort claims premised on allegations that the device in question is unsafe or ineffective. The device at issue in this litigation—the Evergreen Balloon Catheter—is a medical device regulated by the FDA pursuant to the Medical Device Amendments of 1976 (MDA), 21 U.S.C. 360c *et seq.*, to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.* The FDCA identifies three classes of medical

devices, each subject to a different level of regulation. See 21 U.S.C. 360c(a)(1); *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 476-477 (1996). The Evergreen Balloon Catheter is a Class III device, see 21 U.S.C. 360c(a)(1)(C), and is accordingly subject to the most stringent regulatory controls. With exceptions that are not implicated here, the manufacturer of a Class III device must obtain FDA approval of a premarket approval (PMA) application before marketing the device. See 21 U.S.C. 360e(a) (2000 & Supp. IV 2004); *Lohr*, 518 U.S. at 477.[1]

In order to obtain premarket approval for a Class III medical device, a manufacturer must submit a PMA application containing full reports of investigations of the device's safety and effectiveness; a statement of the components and principles of operation of the device; a comprehensive description of the methods of manufacture, processing, packing, and installation of the device; and the proposed labeling for the device. See 21 U.S.C. 360e(c)(1); 21 C.F.R. 814.20. In determining whether to approve a PMA application, the FDA considers the information submitted by the manufacturer as well as other information known to the agency. See 21 C.F.R. 814.45(c). The FDA may also request additional information from the manufacturer, and it may consult with a scientific advisory committee made up of outside experts. 21 C.F.R. 14.171, 814.20(b)(13). The agency conducts a rigorous

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[1] As the Court explained in *Lohr*, see 518 U.S. at 477-478, two categories of Class III devices may be marketed without PMA approval by the FDA. First, devices that were already being marketed for use at the time of the MDA's enactment may continue to be marketed until the FDA issues an applicable regulation requiring submission of a PMA. See 21 U.S.C. 360e(a) (2000 & Supp. IV 2004); 21 U.S.C. 360e(b)(1)(A); *Lohr*, 518 U.S. at 477-478. Second, a new device that is "substantially equivalent" to a device that is already lawfully on the market may enter the market through FDA clearance of a premarket submission commonly referred to as a "510(k)." See 21 U.S.C. 360(k); *Lohr*, 518 U.S. at 478. Those provisions of the FDCA do not apply in this case, since the Evergreen Balloon Catheter is a post-MDA device for which PMA approval was required.

review of requests for premarket approval, devoting an average of 1200 hours to each application. See *Lohr*, 518 U.S. at 477.

The FDA grants premarket approval for a Class III device only if, *inter alia*, the agency finds that there is a "reasonable assurance of safety and effectiveness" when the device is used in accordance with the conditions of use included in the proposed labeling, and that the proposed labeling is neither false nor misleading. 21 U.S.C. 360e(d)(1)(A); see 21 U.S.C. 360e(d)(2)(A), (B) and (D). In determining the safety and effectiveness of a device, the FDA must "weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. 360c(a)(2)(C). The FDA may impose restrictions on the sale or distribution of the device as a condition of premarket approval, see 21 U.S.C. 360e(d)(1)(B); 21 C.F.R. 814.82, and it may impose device-specific restrictions by regulation, see 21 U.S.C. 360j(e)(1). After a manufacturer has received premarket approval for a Class III medical device, it must submit a supplemental application to the FDA before making any changes to the device that affect the device's safety or effectiveness. See 21 U.S.C. 360e(d)(6); 21 C.F.R. 814.39, 814.80. With narrow exceptions, the manufacturer must receive the FDA's approval before making any such changes.[2]

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[2] For a narrow class of changes, the manufacturer may submit a "Changes Being Effected" application, setting out in detail the proposed change and the data or information that supports it. See 21 C.F.R. 814.39(d). Unless the FDA rejects the "Changes Being Effected" application within a specified period, the manufacturer may implement the proposed change prior to FDA action on the application, see 21 C.F.R. 814.39(d)(1), although the FDA retains the authority to reject the application and to require the manufacturer to stop distributing the product with the change. Among the types of changes that are eligible for a "Changes Being Effected" application are labeling changes that add or strengthen a warning, as well as changes in quality control or manufacturing process that provide additional assurance of purity, identity, strength, or reliability of the device. See 21 C.F.R. 814.39(d)(2).

The FDCA contains an express preemption provision. That provision states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. 360k(a). The FDA is authorized to exempt from preemption certain State or local requirements for a device. See 21 U.S.C. 360k(b).

2. The Evergreen Balloon Catheter is a Class III medical device manufactured by respondent Medtronic, Inc. Pet. App. 3a. It is used during angioplasties to open patients' clogged arteries. *Ibid.* The device received premarket approval from the FDA in 1994. *Ibid.* In 1995 and 1996, the FDA approved respondent's supplemental applications for revised labeling for the device. *Id.* at 3a-4a.

Petitioner Charles Riegel suffered extensive injuries after an Evergreen Balloon Catheter ruptured while he was undergoing angioplasty. Pet. App. 4a. He and his wife, petitioner Donna Riegel, brought suit in federal court against respondent. *Ibid.* Petitioners' complaint alleged negligent design, testing, manufacture, distribution, labeling, marketing, and sale of the catheter; strict liability; breach of express warranty; breach of implied warranty; and loss of consortium. *Id.* at 4a-5a. The district court held that all of petitioners' claims except those for negligent manufacturing and breach of express warranty were preempted by 21 U.S.C. 360k(a). See Pet. App. 55a-74a. The court subse-

quently granted respondent's motion for summary judgment on the merits of the non-preempted claims. *Id.* at 75a-91a.

3. The court of appeals affirmed. Pet. App. 1a-54a.

The court of appeals explained that the premarket approval process for Class III medical devices is "lengthy and rigorous," requiring each manufacturer to provide extensive information establishing the safety and effectiveness of its device. See Pet. App. 8a-9a. The court further observed that "[t]here is significant opportunity for interaction between the FDA and the manufacturer over the course of the PMA process," *id.* at 8a, and that the FDA is authorized to impose additional requirements as conditions of premarket approval in order to ensure that the device is safe and effective, *id.* at 9a. The court explained as well that, once the FDA approves an application for premarket approval, federal law requires the manufacturer to comply with the specifications set forth in the application and the approval order. See *ibid.*

In holding that the bulk of petitioners' claims were preempted, the court of appeals construed the term "requirement" in 21 U.S.C. 360k(a)(1) to encompass product specifications set forth in the PMA application that was submitted by respondents and approved by the FDA. See Pet. App. 26a-28a. The court explained that, if the FDA had viewed respondent's proposed product specifications as inadequate to ensure safety and efficacy, the agency could have imposed additional requirements as conditions of premarket approval. *Id.* at 27a-28a. The court recognized that the approved specifications for the Evergreen Balloon Catheter had been fashioned by respondent rather than devised by the FDA, see *id.* at 28a, but it found that fact to be irrelevant to the preemption analysis. The court explained that, "[o]nce the PMA process is complete, all PMA-approved devices are subject to the same federal device-specific regulation: complying with the standards set forth in their individual approved PMA applications." *Ibid.*

The court of appeals further held that the imposition of tort liability based on the allegedly defective character of the device would have the practical effect of subjecting the manufacturer to state-law requirements "different from, or in addition to," the federal requirements embodied in the approved PMA application. Pet. App. 32a, 35a-36a. The court noted that the claims held to be preempted "do not rest on the premise that the particular catheter used during Mr. Riegel's angioplasty deviated from the standards contained in the approved PMA application for the Evergreen Balloon Catheter." *Id.* at 32a. Rather, the court explained,

> a verdict in [petitioners'] favor on any of these claims would represent a finding that the Evergreen Balloon Catheter had not adhered to the various state common law duties implicated by those claims, *e.g.*, that its design did not comport with the duty of due care, or that its labeling did not comport with the duty to warn. Such a verdict would clearly differ from the FDA's PMA approval of the device (and its related packaging, labeling, distribution, and so on) as being reasonably safe and effective, and, moreover, from the FDA's prohibition against making any modifications affecting the device's safety and effectiveness without first obtaining FDA approval.

*Id.* at 33a. The court further noted that its conclusion that such tort claims are preempted is supported by the FDA's position on the preemption question. *Id.* at 37a-38a.

The court of appeals also concluded that the FDA's grant of premarket approval is significantly different, for purposes of preemption analysis, from the substantial-equivalence determination (see note 1, *supra*) that was at issue in *Lohr*. See Pet. App. 24a-27a. The court noted that premarket approval, unlike a finding of substantial equivalence, reflects the FDA's considered judgment that there is reasonable assurance that the device

at issue is safe and effective. See *id.* at 25a. The court further observed that, whereas a substantial-equivalence finding "does not reflect the FDA's determination that the device should 'take any particular form for any particular reason,' the PMA process expressly provides the FDA with the power to require the device to take a particular form in order to be approved as safe and effective." *Id.* at 26a (quoting *Lohr*, 518 U.S. at 493). The court also explained that manufacturers of devices for which a substantial-equivalence finding has been made "have broader latitude to make changes without FDA approval than do manufacturers of PMA[-]approved devices." *Id.* at 26a-27a.[3]

Judge Pooler filed an opinion concurring in part and dissenting in part. Pet. App. 43a-54a. While characterizing the preemption issue presented in this case as a "close question," *id.* at 43a, Judge Pooler would have held that petitioners' claims are not preempted, see *id.* at 50a-53a.

## DISCUSSION

The court of appeals correctly held—in accordance with the FDA's interpretation of the FDCA, see Pet. App. 37a-38a—that the FDA's premarket approval of a Class III medical device imposes federal "requirements" that preclude the imposition of state-law tort liability based on respondent's alleged failure to

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[3] The court of appeals "agree[d] with the district court's conclusion that [petitioners'] negligent manufacturing claim was not preempted, to the extent that it rested on the allegation that the particular Evergreen Balloon Catheter that was deployed during Mr. Riegel's angioplasty had not been manufactured in accordance with the PMA-approved standards." Pet. App. 35a. The court explained that "[a] jury verdict in [petitioners'] favor on this claim would not have imposed state requirements that differed from, or added to, the PMA-approved standards for this device, but would instead have simply sought recovery for [respondent's] alleged deviation from those standards." *Id.* at 35a-36a. The court of appeals affirmed the district court's grant of summary judgment to respondent on the merits of the negligent-manufacturing claim, however, see *id.* at 38a-43a, and petitioners do not challenge that ruling in this Court.

satisfy inconsistent or additional state-law requirements. The Second Circuit's decision in this case accords with the large majority of federal and state appellate rulings on the question presented here. Although one federal court of appeals and one state supreme court have held that comparable tort claims were not preempted, those decisions predate most of the other cases addressing the question, and they were issued without the benefit of FDA's current judgment that premarket approval of a Class III device imposes federal "requirements" that should be given preemptive effect. In light of those intervening developments, the courts that have previously rejected preemption defenses in this context may reconsider their position in an appropriate case. This case, moreover, would not be an appropriate vehicle in which to address the preemption of state tort suits concerning Class III devices that have received PMA approval. See pp. 14-15, *infra*. Review by this Court therefore is not warranted.

**A. The Decision Of The Court Of Appeals Is Correct**

Petitioners contend (Pet. 19-22) that the court of appeals' ruling in this case is inconsistent with this Court's decision in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996). *Lohr*, however, does not govern this case.

1. In *Lohr*, this Court considered the application of the MDA's express preemption provision, 21 U.S.C. 360k, to a tort suit involving a medical device for which the FDA had made a substantial-equivalence determination. See 518 U.S. at 480-481. In rejecting the manufacturer's claim that the suit was preempted, the Court explained that the process by which substantial-equivalence findings are made "is by no means comparable to the PMA process," involving an average of 20 hours of review time in contrast to the 1200 hours spent on the average PMA review. *Id.* at 478-479. The Court also noted the FDA's own admonition that its substantial-equivalence determination

"should not be construed as an endorsement of the [device]'s safety." *Id.* at 480.

The manufacturer in *Lohr* argued that the FDA's promulgation of general standards for labeling and manufacturing of medical devices "pre-empts any and all common-law claims brought by an injured plaintiff against a manufacturer of medical devices." 518 U.S. at 486 (plurality opinion). All Members of this Court agreed that the statute does not impose that blanket prohibition on the imposition of state-law tort liability. See *id.* at 487 (plurality opinion); *id.* at 505 (Breyer, J., concurring in part and concurring in the judgment); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part). The manufacturer also argued, *inter alia*, that the FDA's clearance of a device based on a substantial-equivalence determination preempted suits alleging that the device was defectively designed. See *id.* at 492 (opinion of the Court). In rejecting that contention, the Court explained that "[t]he company's defense exaggerates the importance of the [substantial-equivalence] process," *ibid.*, and that the device at issue had "never been formally reviewed [by the FDA] under the MDA for safety or efficacy," *id.* at 493. Accord *id.* at 513 (O'Connor, J., concurring in part and dissenting in part).

A four-Justice plurality of the *Lohr* Court predicted that any common-law suits preempted by Section 360k would be "few" and "rare." 518 U.S. at 502. In his concurring opinion, however, Justice Breyer stated that "ordinarily, insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care imposed by a state-law tort action." *Id.* at 504-505. Justice Breyer further stated that he was "not convinced that future incidents of MDA pre-emption of common-law claims will be 'few' or 'rare.'" *Id.* at 508. The remaining four Justices "conclude[d] that state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements

would differ from those imposed by the [FDCA]." *Id.* at 509 (O'Connor, J., concurring in part and dissenting in part). Those Justices also expressed disagreement with the plurality's forecast that instances of such preemption would be "rare." *Ibid.* Thus, five Members of the Court in *Lohr* agreed that state tort suits are preempted on essentially the same terms as state prescriptive requirements.

The Court in *Lohr* also noted the significant role of the FDA in defining the MDA's preemptive scope. The Court explained:

> Because the FDA is the federal agency to which Congress has delegated its authority to implement the provisions of the Act, the agency is uniquely qualified to determine whether a particular form of state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress," *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941), and, therefore, whether it should be pre-empted.

518 U.S. at 496 (footnote omitted). The Court concluded that, with respect to the construction of the FDCA's express preemption provision, "[t]he ambiguity in the statute—and the congressional grant of authority to the agency on the matter contained within it—provide a sound basis for giving substantial weight to the agency's view of the statute." *Ibid.* (citation and internal quotation marks omitted).

2. In the instant case, the court of appeals held that the FDA's premarket approval of the Evergreen Balloon Catheter imposed specific federal "requirements" that preempted inconsistent duties sought to be imposed through application of state tort law. See Pet. App. 25a-29a. That holding is correct and is consistent with this Court's decision in *Lohr*.

The FDA's premarket approval for the Evergreen Balloon Catheter was premised on the agency's finding that there was reasonable assurance that the device was safe and effective under the conditions of use prescribed, recommended, or suggested

in the labeling of the device and that the labeling was neither false nor misleading. 21 U.S.C. 360c(a)(2)(B), 360e(d)(1)(A) and (2)(A)-(E); see Pet. App. 25a, 27a-28a. Once the device was approved, moreover, respondent could not lawfully implement any changes that would affect the safety or efficacy of the device without submitting a supplemental application to the FDA (and, in most instances, receiving prior FDA approval). See *id.* at 26a; p. 3 and note 2, *supra*. Because the specifications contained in respondent's application were binding on the manufacturer once the application had been approved, and because the FDA's PMA approval reflected the agency's considered judgment as to the product's safety and efficacy, the court of appeals correctly held that those specifications constitute federal "requirement[s]" within the meaning of Section 360k(a)(1).

Moreover, in determining the safety and effectiveness of a device, the FDA must "weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. 360c(a)(2)(C). The court of appeals' ruling thus is fully consistent with *Lohr*, in which the Court distinguished the facts before it from a case, such as this one, "in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers." 518 U.S. at 501.

As the court of appeals explained, if the FDA had determined that the device as described in respondent's application was not safe and effective, the agency could have conditioned its grant of premarket approval on respondent's agreement to undertake specified modifications. Pet. App. 27a-28a. A product specification devised by the FDA and imposed as a condition of authority to market a medical device would constitute a federal "requirement" that would preempt state efforts to impose inconsistent or

additional common-law duties. The court of appeals correctly recognized that respondent should not be subject to *greater* potential tort liability simply because the FDA had "deemed the PMA application for the Evergreen Balloon Catheter acceptable in its present form" and therefore had declined to impose additional conditions. *Id.* at 28a.

The FDCA also specifically addresses the possibility that new information might come to light that would call into question whether a previously approved device meets the Act's requirements for PMA approval. Once again, however, the FDCA vests responsibility for taking action in the FDA, based on its evaluation of the information and weighing of the relevant considerations. The Act thus authorizes the FDA to withdraw its PMA approval of a device if the agency finds that the device is unsafe or ineffective, or if the agency finds, on the basis of new information evaluated together with information available to it when it approved the application, that the requisite showing of reasonable assurance that the device is safe and effective is lacking, or that the labeling is false or misleading in any particular and was not corrected within a reasonable time after receipt from the FDA of notice of that fact. See 21 U.S.C. 360e(e)(1)(A), (B) and (F). Where the FDA has not taken such action, its approval of the PMA—and the "requirements" that result from that approval—remain in effect.

The court of appeals also correctly held that petitioners' tort suit seeks to impose state "requirement[s]," within the meaning of Section 360k(a), that relate to safety or efficacy and are different from the federal requirements that apply to the Evergreen Balloon Catheter. See Pet. App. 30a-35a. As the court of appeals recognized, this Court in construing similarly worded federal preemption provisions "has held firm to the view that state 'requirements' can be created by state common law actions." *Id.* at 31a; see, *e.g.*, *Bates* v. *Dow Agroscis. LLC*, 544 U.S. 431, 443 (2005); see also *Lohr*, 518 U.S. at 503-504 (Breyer, J., concur-

ring in part and concurring in the judgment); *id.* at 510-512 (O'Connor, J., concurring in part and dissenting in part). The claims that the court of appeals held to be preempted do not rest on the premise that the particular catheter used during Mr. Riegel's angioplasty deviated from the specifications in the approved PMA application. Rather, they all rest on the allegation that the Evergreen Balloon Catheter, in the form approved by the FDA, "is in some way defective and therefore requires modification." Pet. App. 32a. A verdict in petitioners' favor would necessarily reflect a finding that respondent could comply with applicable state-law duties of care only by altering the product specifications or labeling that had been reviewed and approved by the FDA. Imposition of tort liability on the basis of such a finding would entail the application of state-law requirements that are "different from, or in addition to," 21 U.S.C. 360k(a)(1), the federal requirements applicable to the device, and that "relate[] to the safety or effectiveness of the device," 21 U.S.C. 360k(a)(2).

The FDA is the expert agency charged by Congress with balancing the risks and benefits of medical devices under the FDCA, and the accomplishment of its regulatory goals would be undermined if lay judges or juries were permitted to second-guess the scientific judgments it makes in approving a PMA application. When the FDA has concluded that a particular medical device is safe and effective for use and has approved the device for marketing, it would undermine the regulatory scheme established by Congress for a jury adjudicating a state-law claim to determine that the same device is defectively designed. Similarly, when the FDA concludes that a particular warning label strikes an appropriate balance between properly notifying users of potential dangers and ensuring that beneficial and possibly life-saving uses of the device are not deterred, a jury should be precluded from deciding that different warnings ought to have been given.

3. In *Bates*, this Court construed the preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), which provides that a State "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. 136v(b) (quoted in *Bates*, 544 U.S. at 439). FIFRA prohibits the sale of "misbranded" products and states that a pesticide is misbranded if its labeling contains "false or misleading" statements, "does not contain adequate instructions for use," or "omits necessary warnings." *Bates*, 544 U.S. at 438. That misbranding prohibition applies to pesticides that are registered with the Environmental Protection Agency (EPA). *Ibid.* The Court held in *Bates* that FIFRA did not preempt the plaintiffs' state-law damages claim alleging a tortious failure to warn so long as the elements of the state cause of action were substantively equivalent to FIFRA's prohibition on the sale of "misbranded" products. See *id.* at 447. The Court "emphasize[d]," however, that "a state-law labeling requirement must in fact be equivalent to a requirement under FIFRA in order to survive pre-emption." *Id.* at 453.

The FDCA also prohibits the distribution of misbranded devices, see 21 U.S.C. 331(a)-(c), and a device is deemed misbranded if, *inter alia*, "its labeling is false or misleading in any particular," or the device "is dangerous to health when used in the * * * manner, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof." 21 U.S.C. 352(a) and (j). The misbranding prohibition applies to products that have received PMA approval. The federal requirements that result from the PMA process have preemptive effect, however, and as explained below, the possibility of federal misbranding liability does not alter that result. See pp. 15-16, *infra*. In any event, petitioners in their certiorari petition do not advance the theory that their state-law claims are preserved because the relevant state-law requirements parallel the FDCA's

misbranding provisions. Cf. note 4, *infra*. Indeed, petitioners do not even cite the FDCA's misbranding provisions. Nor did the court of appeals address that issue; it considered only whether the PMA approval process itself results in "requirement[s]" under 21 U.S.C. 360k(a), and whether state common law imposes corresponding state "requirement[s]." This case therefore would not present an occasion for the Court to consider the viability of such a theory.

Such a theory would be unavailing in any event. The process of agency review under FIFRA with regard to the label language at issue in *Bates* differs in important respects from the process by which the FDA decides whether to grant premarket approval for particular Class III devices. The plaintiff farmers in *Bates* alleged that the label of a pesticide manufactured by the defendant had failed to warn of the potential for the pesticide to damage the farmers' peanut crops. See 544 U.S. at 434-435. Under FIFRA, EPA reviews pesticides and their labeling to determine whether the pesticide causes unreasonable adverse effects on human health or safety or the environment, but EPA does not evaluate the efficacy of the product, including its potential to harm crops or cause other property damage, and the agency does not review the accuracy of any statements about efficacy on the proposed labeling for the product. *Id.* at 440. EPA therefore had not determined whether the label at issue in *Bates* had adequately warned farmers of the potential for damage to their crops. See *ibid.* (noting that EPA had "never passed on the accuracy of the statement in [the pesticide's] original label recommending the product's use 'in all areas where peanuts are grown'"). In the instant case, by contrast, petitioners' challenge to the safety and efficacy of the Evergreen Balloon Catheter goes directly to matters as to which the FDA conducted a rigorous agency review in the PMA process—a review that culminated in the FDA's finding that the Evergreen Balloon Catheter *does* provide "reasonable assurance of safety and effectiveness"

and that the labeling is not "false or misleading." See 21 U.S.C. 360e(d)(1)(A).[4]

Furthermore, the Court explained in *Bates* that FIFRA does not have a comprehensive goal of "uniformity," but rather "authorizes a relatively decentralized scheme that preserves a broad role for state regulation." 544 U.S. at 450. Under the FDCA, by contrast, the FDA is vested with centralized authority in order to promote uniformity of regulation, including the authority under 21 U.S.C. 360k(b) to decide whether exceptions to preemption of state law should be allowed.

4. In its amicus brief filed at the petition stage at the Court's invitation in *Smith Industries Medical Systems, Inc.* v. *Kernats*, cert. denied, 522 U.S. 1044 (1998), the United States took the position that the FDA's grant of premarket approval for a medical device does not itself establish federal "requirement[s]" for the device within the meaning of Section 360k(a). U.S. Br. at 14-17, *Kernats*, *supra* (No. 96-1405). The position taken in the government's brief in *Kernats* was based upon the FDA's interpretation of the MDA and the agency's characterization of its role in the administrative process at that time, as reflected in a pro-

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[4] As a general matter, 21 U.S.C. 360k(a) does not preempt common-law suits in which the duty of care is defined by federal law and a State simply provides additional remedies for violations of the federal standard. See *Lohr*, 518 U.S. at 494-497; *id.* at 513 (O'Connor, J., concurring in part and dissenting in part). Consistent with that principle, the court of appeals correctly held that petitioners' "negligent manufacturing claim was not preempted, to the extent that it rested on the allegation that the particular Evergreen Balloon Catheter that was deployed during Mr. Riegel's angioplasty had not been manufactured in accordance with the PMA-approved standards." Pet. App. 35a; see note 3, *supra*. Adjudication of the negligent-manufacturing claim would not implicate any FDA finding, since the agency has made no individualized determination whether a particular catheter conforms to the approved product specifications. With respect to the adequacy of the product specifications themselves, however, the FDA found that there was reasonable assurance of safety and effectiveness of the device, and that the labeling was not false or misleading, when it approved respondent's PMA application.

posed interpretive rule that was appended to the brief and published shortly after the brief was filed. See 62 Fed. Reg. 65,384, 65,387 (1997). That proposed rule, however, was subsequently withdrawn. See 63 Fed. Reg. 39,789 (1998).

The FDA has since reexamined the issue and determined that the position it announced at the time of the filing in *Kernats* was erroneous. The FDA's current position was set forth in an amicus brief filed by the United States on May 14, 2004, in *Horn* v. *Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004). See *Horn*, 376 F.3d at 170-173 (discussing the FDA's position set forth in the amicus filing). The government explained in the amicus brief in *Horn* that the prior position did not adequately reflect either the highly detailed nature of the process by which the FDA reviews applications for premarket approval, or the constraints that premarket approval places on manufacturers who subsequently wish to change a device's specifications. U.S. Amicus Br., *Horn* v. *Thoratec*, *supra*, at 28 (No. 02-4597); see generally *id.* at 6-11, 15-17, 20-21, 25-27. The government's position in *Kernats* is also inconsistent with the risk-management principles that the FDA currently follows, which recognize that over-warning may be detrimental to the public health. See, *e.g.*, *id.* at 29; 71 Fed. Reg. 3935 (2006) (explaining that additional state requirements governing disclosure of drug-risk information "can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use," and that "[e]xaggeration of risk could discourage appropriate use of a beneficial drug"). This Court held in *Lohr* that the FDA's views on preemption questions under 21 U.S.C. 360k are entitled to "substantial weight." 518 U.S. at 496.

### B. The Decision Of The Court Of Appeals Does Not Warrant Review

The Second Circuit's resolution of the preemption question raised in this case is consistent with the rulings of the great majority of federal and state appellate courts that have addressed the issue since *Lohr*. During that period, all but one of the federal courts of appeals to decide the issue have held that premarket approval of a medical device preempts state tort claims challenging the safety or efficacy of a product that was designed, manufactured, and labeled in compliance with the terms of the premarket approval order. See Pet. App. 24a-38a; *Horn*, 376 F.3d at 166-180; *McMullen* v. *Medtronic, Inc.*, 421 F.3d 482, 486-490 (7th Cir. 2005), cert. denied, 126 S. Ct. 1464 (2006); *Martin* v. *Medtronic, Inc.*, 254 F.3d 573, 575-585 (5th Cir. 2001), cert. denied, 534 U.S. 1078 (2002); *Kemp* v. *Medtronic, Inc.*, 231 F.3d 216, 221-237 (6th Cir. 2000), cert. denied, 534 U.S. 818 (2001); see also *Brooks* v. *Howmedica, Inc.*, 273 F.3d 785, 791-799 (8th Cir. 2001) (en banc) (finding federal preemption based on approval of device pursuant to regulatory precursor of premarket approval process), cert. denied, 535 U.S. 1056 (2002); but see *Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367, 1369-1382 (11th Cir. 1999) (holding that comparable claims were not preempted). Similarly, all but one of the state supreme courts to rule on this issue have held that analogous suits are preempted by federal law. See *Green* v. *Dolsky*, 685 A.2d 110, 115-118 (Pa. 1996), cert. denied, 520 U.S. 1168, and 520 U.S. 1212 (1997); *Fry* v. *Allergan Med. Optics*, 695 A.2d 511, 514-517 (R.I.), cert. denied, 522 U.S. 952 (1997); *Worthy* v. *Collagen Corp.*, 967 S.W.2d 360, 366-377 (Tex.), cert. denied, 524 U.S. 954 (1998); but see *Weiland* v. *Telectronics Pacing Sys., Inc.*, 721 N.E.2d 1149, 1151-1154 (Ill. 1999).[5]

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[5] Petitioners contend that three additional cases are in conflict with the weight of authority holding that the FDA's premarket approval of a medical

Moreover, the decisions in *Goodlin* and *Weiland*, which rejected preemption defenses similar to that raised by respondent here, were issued in 1999, when the law in this area was relatively undeveloped and when the stated view of the FDA, as set forth in the amicus brief filed by the United States in *Kernats* (see pp. 16-17, *supra*), was that the PMA approval process does not impose "requirement[s]" under 21 U.S.C. 360k(a) and that claims like petitioners' were not preempted. Since that time, several federal courts of appeals and state supreme courts have sustained analogous preemption defenses, and no such court has issued a contrary ruling. And since that time, the FDA has reassessed the issue and has concluded that the PMA approval process does result in "requirements" and that state tort claims challenging the safety or efficacy of PMA-approved devices are therefore preempted under 21 U.S.C. 360k(a). See p. 17, *supra*.

The courts in *Goodlin* and *Weiland* had no opportunity to take into account the later-developing majority view among the federal and state appellate courts. Nor did the courts in *Goodlin* and *Weiland* have the opportunity to consider the current position of the FDA, the expert agency charged by Congress with administering the FDCA. In any future decision concerning Section 360k's preemptive scope, those courts would be required

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device preempts state tort claims under Section 360k(a). See Pet. 3 (citing *Oja* v. *Howmedica, Inc.*, 111 F.3d 782 (10th Cir. 1997), and *Nichoff* v. *Surgidev Corp.*, 950 S.W.2d 816 (Ky. 1997), cert. denied, 523 U.S. 1005 (1998)); Pet. 14 (citing *State ex rel. Miller* v. *New Womyn, Inc.*, 679 N.W.2d 593 (Iowa 2004)). Those cases are readily distinguishable. None of them involved devices for which the FDA had approved a PMA application before the conduct that was alleged to be the basis for liability. See *Oja*, 111 F.3d at 787, 789; *Nichoff*, 950 S.W.2d at 817; *New Womyn*, 679 N.W.2d at 597. In *Oja* and *Nichoff*, moreover, the courts held that liability under state tort law or other state law of general applicability would not result in the imposition of a state "requirement," see *Oja*, 111 F.3d at 789; *Nichoff*, 950 S.W.2d at 822—a premise that was subsequently rejected by this Court in *Bates*, see 544 U.S. at 443; p. 12, *supra*.

to give "substantial weight" to the FDA's position. *Lohr*, 518 U.S. at 496.

In light of those intervening developments, the Eleventh Circuit and the Illinois Supreme Court may reconsider their earlier approach should this issue arise in future cases litigated within those jurisdictions. Under these circumstances, the narrow split in authority does not warrant this Court's review. This Court has repeatedly denied certiorari petitions that presented questions concerning the preemptive effect of the FDA's issuance of premarket approval for Class III medical devices. See *McMullen* v. *Medtronic, Inc.*, 126 S. Ct. 1464 (2006); *Knisley* v. *Medtronic, Inc.*, 126 S. Ct. 420 (2005); *Brooks* v. *Howmedica, Inc.*, 535 U.S. 1056 (2002); *Martin* v. *Medtronic, Inc.*, 534 U.S. 1078 (2002); *Kemp* v. *Medtronic, Inc.*, 534 U.S. 818 (2001); *Worthy* v. *Collagen Corp.*, 524 U.S. 954 (1998); *Fry* v. *Allergan Med. Optics*, 522 U.S. 952 (1997); *Green* v. *Dolsky*, 520 U.S. 1168 (1997); *Collagen Corp.* v. *Green*, 520 U.S. 1212 (1997). There is no reason for a different result here.

## CONCLUSION

The petition for a writ of certiorari should be denied.

Respectfully submitted.

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MAY 2007

RECORD AND BRIEFS

(24)

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AUG 27 2007
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SUPREME COURT, U.S.

No. 06-179

IN THE

# Supreme Court of the United States

CHARLES R. RIEGEL and DONNA S. RIEGEL,
*Petitioners,*

v.

MEDTRONIC, INC.,
*Respondent.*

On Writ of Certiorari to the
United States Court of Appeals for the Second Circuit

## JOINT APPENDIX

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Petition for Certiorari Filed: August 3, 2006
Certiorari Granted: June 25, 2007

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# TABLE OF CONTENTS

Page

Relevant docket entries

United States District Court for the Northern District of New York, No. 99-CV-0649 ..... 1

United States Court of Appeals for the Second Circuit, Case No. 04-0412-cv ..... 7

Exhibits to Affidavit of James Shy in Support of Defendant's Motion for Summary Judgment, United States District Court for the Northern District of New York, No. 99-CV-0649, dated January 26, 2000, and filed March 29, 2000

Exhibit E - Letter from FDA dated March 25, 1988, and attached "Conditions of Approval" dated November 19, 1986 ..... 9

Exhibit F - Letter from FDA dated August 30, 1994 ..... 16

Exhibit G - Letter from FDA dated April 27, 1995, and attached "Conditions of Approval" dated October 7, 1994 ..... 18

Exhibit H - Letter from FDA dated April 27, [year illegible] and attached "Conditions of Approval" dated October 7, 1994 ..... 26

Exhibit I - Letter from FDA dated April 8, 1996 .. 34

The following opinions and order have been omitted in printing this joint appendix because they appear on the following pages in the appendix to the Petition for Certiorari:

Memorandum-Decision and Order of the United States District Court for the Northern District of New York dated March 14, 2002 ..... 55a

Memorandum-Decision and Order of the United States District Court for the Northern District of New York dated December 2, 2003 ..... 75a

Decision of the United States Court of Appeals for the Second Circuit dated May 16, 2006 ..... 1a



UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

Docket No. 1:99-cv-00649-LEK-RFT

CHARLES R. RIEGEL AND DONNA S. RIEGEL, Plaintiffs,

v.

MEDTRONIC, INC., Defendant.

DOCKET ENTRIES

| Filing Date | # | Docket Text |
|---|---|---|
| 04/29/1999 | 1 | COMPLAINT filed; FILING FEE $ 150.00 RECEIPT # 41768 ; Service deadline 6/28/99 for Medtronic, Inc. (wbl) (Entered: 04/30/1999) |
| 04/29/1999 | | SUMMONS(ES) issued for Medtronic, Inc. (wbl) (Entered: 04/30/1999) |
| | | * * * * * |
| 06/09/1999 | 3 | ANSWER to Complaint by Medtronic, Inc. (Attorney Richard Bakalor ); jury trial demanded. (fce) (Entered: 06/09/1999) |
| 06/18/1999 | 4 | AMENDED ANSWER to Complaint by Medtronic, Inc. : amends [3-1] answer; jury demand (fce) (Entered: 06/18/1999) |
| | | * * * * * |

| | | |
|---|---|---|
| 03/29/2000 | 17 | Statement of Material Facts in Support of [16-1] motion for Summary Judgment and/or Partial Summary Judgment, [16-2] motion to Dismiss plaintiff's Breach of Express Warranty Claim filed by Medtronic, Inc. (tab) (Entered: 03/29/2000) |
| 03/29/2000 | 18 | AFFIDAVIT by Medtronic, Inc. Re: in support of [16-1] motion for Summary Judgment and/or Partial Summary Judgment, [16-2] motion to Dismiss plaintiff's Breach of Express Warranty Claim (tab) (Entered: 03/29/2000) |
| 03/29/2000 | 19 | MEMORANDUM by Medtronic, Inc. in support of [16-1] motion for Summary Judgment and/or Partial Summary Judgment, [16-2] motion to Dismiss plaintiff's Breach of Express Warranty Claim (tab) (Entered: 03/29/2000) |
| 03/29/2000 | 20 | Exhibits in support of defendant's motion for summary judgment and to dismiss claim. (tab) (Entered: 03/29/2000) |



| | | |
|---|---|---|
| 03/29/2000 | 21 | Statement of Material Facts in Response to 's 6-1] motion for Summary Judgment and/or Partial Summary Judgment, [16-2] motion to Dismiss plaintiff's Breach of Express Warranty Claim filed by Charles R. Riegel, Donna S. Riegel (tab) (Entered: 03/29/2000) |
| 03/29/2000 | 22 | ANSWERING AFFIDAVIT by Wayne P. Smith as to Charles R. Riegel, Donna S. Riegel Re: in OPPOSITION to [16-1] motion for Summary Judgment and/or Partial Summary Judgment, [16-2] motion to Dismiss plaintiff's Breach of Express Warranty Claim (tab) Modified on 03/29/2000 (Entered: 03/29/2000) |
| 03/29/2000 | 23 | MEMORANDUM OF LAW by Charles R. Riegel, Donna S. Riegel in opposition to [16-1] motion for Summary Judgment and/or Partial Summary Judgment, [16-2] motion to Dismiss plaintiff's Breach of Express Warranty Claim (tab) (Entered: 03/29/2000) |
| 03/29/2000 | 24 | REPLY AFFIDAVIT by Medtronic, Inc. to response to [16-1] motion for Summary Judgment and/or Partial Summary Judgment, [16-2] motion to Dismiss plaintiff's Breach of Express Warranty Claim (tab) (Entered: 03/29/2000) |

| | | |
|---|---|---|
| 03/29/2000 | 25 | REPLY Statement of Material Facts in Support of [16-1] motion for Summary Judgment and/or Partial Summary Judgment, [16-2] motion to Dismiss plaintiff's Breach of Express Warranty Claim filed by Medtronic, Inc. (tab) (Entered: 03/29/2000) |
| 03/29/2000 | 26 | REPLY MEMORANDUM by Medtronic, Inc. in further support of [16-1] motion for Summary Judgment and/or Partial Summary Judgment, [16-2] motion to Dismiss plaintiff's Breach of Express Warranty Claim (tab) (Entered: 03/29/2000) |
| | | * * * * * |
| 05/23/2000 | 29 | SUR-REPLY RESPONSE by Charles R. Riegel, Donna S. Riegel Reply Memorandum to [16-1] motion for Summary Judgment and/or Partial Summary Judgment, [16-2] motion to Dismiss plaintiff's Breach of Express Warranty Claim (tab) (Entered: 05/23/2000) |
| | | * * * * * |



| | | |
|---|---|---|
| 03/18/2002 | 33 | MEMORANDUM-DECISION AND ORDER granting in part, denying in part [16-1] motion for Summary Judgment and/or Partial Summary Judgment, denying [16-2] motion to Dismiss plaintiff's Breach of Express Warranty Claim ( signed by Judge Lawrence E. Kahn ) Date Entered: 3/18/02 (tab) (Entered: 03/18/2002) |
| | | * * * * * |
| 05/23/200[3] | 50 | AFFIDAVIT by Ted Milo as to Charles R. Riegel, Donna S. Riegel Re: in opposition to [47-1] motion for Summary Judgment (tab) (Entered: 05/27/2003) |
| | | * * * * * |
| 12/11/2003 | 60 | Memorandum-Decision and ORDER granting [47] Motion for Summary Judgment and Dismissing action. Signed by Judge Lawrence E. Kahn on 12/2/03. (tab, ) (Entered: 12/16/2003) |
| 12/11/2003 | 61 | JUDGMENT in favor of Defendants against Plaintiffs (tab, ) (Entered: 12/16/2003) |

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| 01/08/2004 | 62 | NOTICE OF APPEAL as to [60] Order on Motion for Summary Judgment, [61] Judgment by Charles R. Riegel, Donna S. Riegel. Filing fee $ 255, receipt number 70951. (jel, ) (Entered: 01/09/2004) |

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UNITED STATES COURT OF APPEALS
FOR THE SECOND CIRCUIT

Docket No. 04-0412-cv

CHARLES R. RIEGEL AND DONNA S. RIEGEL,
Plaintiffs-Appellants,

v.

MEDTRONIC, INC., Defendant-Appellee.

DOCKET ENTRIES

| | |
|---|---|
| 1/22/04 | Copy of notice of appeal and district court docket entries on behalf of APPELLANT'S Charles Riegel and- Donna Riegel, filed. Forms C and D due on 1/24/04. [Entry date Feb 4 2004 ] [TM] |

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| 3/8/05 | APPELLANTS Charles Riegel and Donna Riegel, brief FILED with proof of service. [Entry date Mar 31 2005 ] [TM] |
| 3/8/05 | APPELLANTS Charles Riegel and Donna Riegel, appendix filed w/pfs.(three volumes) [Entry date Mar 31 2005 ] [TM] |
| 3/8/05 | APPELLANTS Charles Riegel and Donna Riegel, special appendix filed (w/pfs) [Entry date Mar 31 2005 ] [TM] |

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| 5/10/05 | APPELLEE Medtronic, Inc., brief with Addendum, filed with proof of service. [Entry date May 11 2005 ] [TM] |
| 5/18/05 | AMICUS CURIAE Product Liability Advisory Council, brief filed with proof of service. [Entry date May 26 2005 ] [TM] |
| 5/27/05 | APPELLANTS Charles Riegel and Donna Riegel, |

| | |
|---|---|
| | reply brief filed with proof of service. [Entry date Jun 7 2005 ] [TM] |
| | * * * * * |
| 12/15/05 | Case heard before POOLER, KATZMANN, PARKER, C.JJ. CD dated: December 15, 2005. [Entry date Dec 15 2005 ] [AG] |
| 5/9/06 | APPELLEE Medtronic, Inc., 28(J) letter received. [Entry date May 10 2006 ] [TM] |
| | * * * * * |
| 5/16/06 | Judgment of the district court is AFFIRMED by published signed opinion filed. (RAK) [Entry date May 16 2006 ] [TM] |
| 5/16/06 | Judge POOLER dissents in a separate opinion, filed. [Entry date May 16 2006 ] [TM] |
| 5/16/06 | Judgment filed. [Entry date May 16 2006 ] [TM] |
| | * * * * * |
| 6/6/06 | Judgment MANDATE ISSUED. CLOSED [Entry date Jun 6 2006 ] [TM] |
| | * * * * * |
| 8/1/06 | Errata sheet re: filed. [Entry date Aug 2 2006 ] [TM] |
| | * * * * * |
| 7/2/07 | Letter dated 6-25-07 from the Supreme Court advising of order GRANTING petition for writ of certiorari by APPELLANTS Charles Riegel and Donna Riegel, , filed. (Supreme Court # 06-179) [Entry date Jul 5 2007 ] [TM] |
| 7/2/07 | Writ of Certiorari GRANTED. [Entry date Jul 5 2007 ] [TM] |

Exhibits to Affidavit of James Shy in Support of Defendant's Motion for Summary Judgment, United States District Court for the Northern District of New York, No. 99-CV-0649, dated January 26, 2000, and filed March 29, 2000

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
8757 Georgia Avenue
Silver Spring MD 20910

MAR 25 1988

Ronald J. Solar, Ph.D.
Vice President and Technical Director
Versaflex Delivery Systems, Inc.
4060 Sorrento Valley Blvd.
San Diego, California 92121

Re: P870036
Versaflex™ Buchbinder™ Omniflex™ PTCA Catheter System
Filed: June 16, 1987
Amended: October 23, 1987 and January 22, 1988

Dear Dr. Solar:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its review of your premarket approval application (PMA) for the Versaflex™ Buchbinder™ Omniflex™ PTCA Catheter System. This device is indicated in patients with coronary artery disease who are acceptable candidates for coronary artery bypass graft surgery, in addition to meeting one or more of the following criteria listed below:

1. Single-vessel atherosclerotic coronary artery disease that is concentric, discrete, subtotal, noncalcified, and accessible to a dilatation catheter.

2. Multiple-vessel coronary artery disease under certain circumstances.

3. Coronary artery disease of the native coronary arteries

and/or coronary artery bypass grafts of some patients who have previously undergone coronary artery bypass graft surgery, have recurrence of symptoms, and (a) progression of disease, or (b) stenosis and closure of the grafts.

The PMA is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device upon receipt of this letter. Expiration dating for this device has been established and approved at 6 months.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (act) under authority of section 515(d)(1)(B)(ii) of the act.

CDRH will publish a notice of its decision to approve your PMA in the FEDERAL REGISTER. The notice will state that a summary of the safety and effectiveness data upon which the approval is based is available to the public upon request. In addition, the notice will state that a copy of all approved labeling (which may be a draft of the final labeling) is available for public inspection at the CDRH. Within 30 days of publication of the notice of approval in the FEDERAL REGISTER, any interested person may seek review of this decision by requesting an opportunity for administrative review, either through a hearing or review by an independent advisory committee, under section 515(g) of the Federal Food, Drug, and Cosmetic Act.

Failure to comply with the conditions of approval invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the act.

All required documents must be submitted in triplicate, unless otherwise specified, to the address below and shall reference the



above PMA number to expedite processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
8757 Georgia Avenue
Silver Spring, Maryland 20910

If you have any questions concerning this approval order, please contact Ms. Nadine Y. Rosile, at (301) 427-7371.

Sincerely yours,

/s/
Kshitij Mohan, Ph.D.
Director
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

BEST AVAILABLE COPY

REVISED: November 19, 1986

## CONDITIONS OF APPROVAL

Approved Labeling. As soon as possible, and before commercial distribution of your device, submit two copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the Food and Drug Administration (FDA), Center for Devices and Radiological Health, PMA Document Mail Center (HFZ-401), 8757 Georgia Avenue, Silver Spring, Maryland 20910.

Advertisement. No advertisement and other descriptive printed material issued by the application or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If FDA has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

Premarket Approval Application (PMA) Supplement. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or for which FDA has advised in an advisory opinion or in correspondence in accordance with 21 CFR 814.39(e) that an alternate submission is permitted. A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices (51 FR 26342) published in the Federal Register of July 22, 1986.



Postapproval Reports. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the Food and Drug Administration, Center for Devices and Radiological Health, PMA Document Mail Center (HFZ-401), 8757 Georgia Avenue, Silver Spring, Maryland 20910. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) Published reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two

copies of each identified report when so notified by FDA.

Adverse Reaction and Device Defect Reporting. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified as an "Adverse Reaction Report" or "Device Defect Report", as applicable, to the Food and Drug Administration, Center for Devices and Radiological Health, 8757 Georgia Avenue, Silver Spring, Maryland 20910 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mixup of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occuring [sic] with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance procedures described in the approved labeling, all such events known to the applicant shall be included in the



Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
1390 Piccard Drive
Rockville MD 20850

AUG 30 1994

Mr. Timothy J. Johnson [date stamp omitted in printing]
Regulatory Affairs Manager
Medtronic Interventional Vascular
9410 Carroll Park Drive
San Diego, California 92121-2256

Re: P870036/S30
Medtronic® Evergreen™ PTCA Catheters
Filed: March 9, 1994
Amended: April 11 and August 18, 1994

Dear Mr. Johnson:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your premarket approval application (PMA) supplement, which requested approval for a new model of PTCA Catheter. The devices will be marketed under the trade name Medtronic® Evergreen™ PTCA Catheters and are indicated for PTCA. Based upon the information submitted, the PMA supplement is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device as modified by your PMA supplement upon receipt of this letter.

Failure to comply with the conditions of approval as attached invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the Federal Food, Drug, and Cosmetic Act.



You are reminded that as soon as possible, and before commercial distribution of your device, that you must submit an amendment to this PMA submission with copies of all approved labeling in final printed form.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
1390 Piccard Drive
Rockville, Maryland 20850

If you have questions concerning this approval order, please contact Glenn N. Byrd at (301) 594-2726.

Sincerely yours,

/s/
Thomas J. Callahan, Ph.D.
Acting Director
Division of Cardiovascular,
Respiratory, and Neurological
Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 1995

Mr. Kenneth Keown
Senior Regulatory Specialist
Medtronic Interventional Vascular
9410 Carroll Park Drive
San Diego, California 92121-2256

Re: P870036/S35
Versaflex™ Buchbinder™ Omniflex™ PTCA Catheter System
Medtronic® 18K®, 14K®, Evergreen™, Falcon™, Panther™, and Spirit® PTCA Catheters
Filed: April 7, 1995

Dear Mr. Keown:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your premarket approval application (PMA) supplement, which requested approval for revised labeling. Based upon the information submitted, the PMA supplement is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device as modified by your PMA supplement upon receipt of this letter.

The sale, distribution, and use of this device are restricted to prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must



not violate sections 502(q) and (r) of the act.

Failure to comply with the conditions of approval as attached invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the Federal Food, Drug, and Cosmetic Act.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have questions concerning this approval order, please contact Glenn N. Byrd at (301) 443-8243.

Sincerely yours,

/s/
Thomas J. Callahan, Ph.D.
Acting Director
Division of Cardiovascular, Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

[date stamp omitted in printing]

Issued: 10-7-94

## CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the application or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.



All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the **addition** of, but **not the replacement** of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgement by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgement is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. **This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.**

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test

results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.



ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mixup of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance

procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

(1) may have caused or contributed to a death or serious injury or

(2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you



shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-544)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, Room 3083
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the above address or by telephoning (301) 594-2735.

DEPARTMENT OF HEALTH & HUMAN SERVICES
Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 27 [year illegible]

Ms. Kathleen T. Boehm
Regulatory Affairs Specialist
Medtronic Interventional Vascular
9410 Carroll Park Drive
San Diego, California 92121-2256

Re: P870036/S32
Versaflex™ Buchbinder™ Omniflex™ PTCA Catheter System
Medtronic® Evergreen™ 40 Coronary Balloon Dilatation Catheter
Filed: October 17, 1994

Dear Ms. Boehm:

The Center for Devices and Radiological Health (CDRH) of the Food and Drug Administration (FDA) has completed its evaluation of your premarket approval application (PMA) supplement, which requested approval for: (1) a 40 mm long balloon version of the Evergreen™ PTCA catheter which incorporates an alternate strain relief assembly; and (2) an alternate strain relief assembly for use on the Evergreen™ and the Evergreen™ 30 PTCA Catheters. Based upon the information submitted, the PMA supplement is approved subject to the conditions described below and in the "Conditions of Approval" (enclosed). You may begin commercial distribution of the device as modified by your PMA supplement upon receipt of this letter.

The sale, distribution, and use of this device are restricted to



prescription use in accordance with 21 CFR 801.109 within the meaning of section 520(e) of the Federal Food, Drug, and Cosmetic Act (the act) under the authority of section 515(d)(1)(B)(ii) insofar as the sale, distribution, and use must not violate sections 502(q) and (r) of the act.

Failure to comply with the conditions of approval as attached invalidates this approval order. Commercial distribution of a device that is not in compliance with these conditions is a violation of the Federal Food, Drug, and Cosmetic Act.

All required documents should be submitted in triplicate, unless otherwise specified, to the address below and reference the above PMA number to facilitate processing.

PMA Document Mail Center (HFZ-401)
Center for Devices and Radiological Health
Food and Drug Administration
9200 Corporate Blvd.
Rockville, Maryland 20850

If you have questions concerning this approval order, please contact Glenn N. Byrd at (301) 443-8243.

Sincerely yours,

/s/
Thomas J. Callahan, Ph.D.
Acting Director
Division of Cardiovascular, Respiratory, and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

[date stamps omitted in printing]

Issued: 10-7-94

## CONDITIONS OF APPROVAL

APPROVED LABELING. As soon as possible, and before commercial distribution of your device, submit three copies of an amendment to this PMA submission with copies of all approved labeling in final printed form to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration (FDA), 9200 Corporate Blvd., Rockville, Maryland 20850.

ADVERTISEMENT. No advertisement or other descriptive printed material issued by the application or private label distributor with respect to this device shall recommend or imply that the device may be used for any use that is not included in the FDA approved labeling for the device. If the FDA approval order has restricted the sale, distribution and use of the device to prescription use in accordance with 21 CFR 801.109 and specified that this restriction is being imposed in accordance with the provisions of section 520(e) of the act under the authority of section 515(d)(1)(B)(ii) of the act, all advertisements and other descriptive printed material issued by the applicant or distributor with respect to the device shall include a brief statement of the intended uses of the device and relevant warnings, precautions, side effects and contraindications.

PREMARKET APPROVAL APPLICATION (PMA) SUPPLEMENT. Before making any change affecting the safety or effectiveness of the device, submit a PMA supplement for review and approval by FDA unless the change is of a type for which a "Special PMA Supplement-Changes Being Effected" is permitted under 21 CFR 814.39(d) or an alternate submission is permitted in accordance with 21 CFR 814.39(e). A PMA supplement or alternate submission shall comply with applicable requirements under 21 CFR 814.39 of the final rule for Premarket Approval of Medical Devices.



All situations which require a PMA supplement cannot be briefly summarized, please consult the PMA regulation for further guidance. The guidance provided below is only for several key instances.

A PMA supplement must be submitted when unanticipated adverse effects, increases in the incidence of anticipated adverse effects, or device failures necessitate a labeling, manufacturing, or device modification.

A PMA supplement must be submitted if the device is to be modified and the modified device should be subjected to animal or laboratory or clinical testing designed to determine if the modified device remains safe and effective.

A "Special PMA Supplement - Changes Being Effected" is limited to the labeling, quality control and manufacturing process changes specified under 21 CFR 814.39(d)(2). It allows for the **addition** of, but **not the replacement** of previously approved, quality control specifications and test methods. These changes may be implemented before FDA approval upon acknowledgement by FDA that the submission is being processed as a "Special PMA Supplement - Changes Being Effected." This acknowledgement is in addition to that issued by the PMA Document Mail Center for all PMA supplements submitted. **This procedure is not applicable to changes in device design, composition, specifications, circuitry, software or energy source.**

Alternate submissions permitted under 21 CFR 814.39(e) apply to changes that otherwise require approval of a PMA supplement before implementation of the change and include the use of a 30-day PMA supplement or annual postapproval report. FDA must have previously indicated in an advisory opinion to the affected industry or in correspondence with the applicant that the alternate submission is permitted for the change. Before such can occur, FDA and the PMA applicant(s) involved must agree upon any needed testing protocol, test

results, reporting format, information to be reported, and the alternate submission to be used.

POSTAPPROVAL REPORTS. Continued approval of this PMA is contingent upon the submission of postapproval reports required under 21 CFR 814.84 at intervals of 1 year from the date of approval of the original PMA. Postapproval reports for supplements approved under the original PMA, if applicable, are to be included in the next and subsequent annual reports for the original PMA unless specified otherwise in the approval order for the PMA supplement. Two copies identified as "Annual Report" and bearing the applicable PMA reference number are to be submitted to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850. The postapproval report shall indicate the beginning and ending date of the period covered by the report and shall include the following information required by 21 CFR 814.84:

(1) Identification of changes described in 21 CFR 814.39(a) and changes required to be reported to FDA under 21 CFR 814.39(b).

(2) Bibliography and summary of the following information not previously submitted as part of the PMA and that is known to or reasonably should be known to the applicant:

(a) unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices ("related" devices include devices which are the same or substantially similar to the applicant's device); and

(b) reports in the scientific literature concerning the device.

If, after reviewing the bibliography and summary, FDA



concludes that agency review of one or more of the above reports is required, the applicant shall submit two copies of each identified report when so notified by FDA.

ADVERSE REACTION AND DEVICE DEFECT REPORTING. As provided by 21 CFR 814.82(a)(9), FDA has determined that in order to provide continued reasonable assurance of the safety and effectiveness of the device, the applicant shall submit 3 copies of a written report identified, as applicable, as an "Adverse Reaction Report" or "Device Defect Report" to the PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Blvd., Rockville, Maryland 20850 within 10 days after the applicant receives or has knowledge of information concerning:

(1) A mixup of the device or its labeling with another article.

(2) Any adverse reaction, side effect, injury, toxicity, or sensitivity reaction that is attributable to the device and

(a) has not been addressed by the device's labeling or

(b) has been addressed by the device's labeling, but is occurring with unexpected severity or frequency.

(3) Any significant chemical, physical or other change or deterioration in the device or any failure of the device to meet the specifications established in the approved PMA that could not cause or contribute to death or serious injury but are not correctable by adjustments or other maintenance procedures described in the approved labeling. The report shall include a discussion of the applicant's assessment of the change, deterioration or failure and any proposed or implemented corrective action by the applicant. When such events are correctable by adjustments or other maintenance

procedures described in the approved labeling, all such events known to the applicant shall be included in the Annual Report described under "Postapproval Reports" above unless specified otherwise in the conditions of approval to this PMA. This postapproval report shall appropriately categorize these events and include the number of reported and otherwise known instances of each category during the reporting period. Additional information regarding the events discussed above shall be submitted by the applicant when determined by FDA to be necessary to provide continued reasonable assurance of the safety and effectiveness of the device for its intended use.

REPORTING UNDER THE MEDICAL DEVICE REPORTING (MDR) REGULATION. The Medical Device Reporting (MDR) Regulation became effective on December 13, 1984, and requires that all manufacturers and importers of medical devices, including in vitro diagnostic devices, report to FDA whenever they receive or otherwise became aware of information that reasonably suggests that one of its marketed devices

(1) may have caused or contributed to a death or serious injury or

(2) has malfunctioned and that the device or any other device marketed by the manufacturer or importer would be likely to cause or contribute to a death or serious injury if the malfunction were to recur.

The same events subject to reporting under the MDR Regulation may also be subject to the above "Adverse Reaction and Device Defect Reporting" requirements in the "Conditions of Approval" for this PMA. FDA has determined that such duplicative reporting is unnecessary. Whenever an event involving a device is subject to reporting under both the MDR Regulation and the "Conditions of Approval" for this PMA, you



shall submit the appropriate reports required by the MDR Regulation and identified with the PMA reference number to the following office:

Division of Surveillance Systems (HFZ-544)
Center for Devices and Radiological Health
Food and Drug Administration
1350 Piccard Drive, Room 3083
Rockville, Maryland 20850
Telephone (301) 594-2735

Events included in periodic reports to the PMA that have also been reported under the MDR Regulation must be so identified in the periodic report to the PMA to prevent duplicative entry into FDA information systems.

Copies of the MDR Regulation and an FDA publication entitled, "An Overview of the Medical Device Reporting Regulation," are available by written request to the above address or by telephoning (301) 594-2735.

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No. 06-179

IN THE

# Supreme Court of the United States

CHARLES R. RIEGEL and DONNA S. RIEGEL,
*Petitioners,*

v.

MEDTRONIC, INC.,
*Respondent.*

On Writ of Certiorari to the
United States Court of Appeals for the Second Circuit

## BRIEF FOR PETITIONERS

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August 2007

## QUESTION PRESENTED

Whether the express preemption provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), preempts state-law claims seeking damages for injuries caused by medical devices that received premarket approval from the Food and Drug Administration.

## TABLE OF CONTENTS

Page

QUESTION PRESENTED ..... i

TABLE OF AUTHORITIES ..... iv

INTRODUCTION ..... 1

JURISDICTION ..... 1

STATUTES AND REGULATIONS INVOLVED ..... 1

STATEMENT OF THE CASE ..... 1

A. The Medical Device Amendments ..... 2

B. State Regulatory Activity And Preemption Under The MDA ..... 6

C. The Decision In *Medtronic v. Lohr* ..... 8

D. Factual Background And Proceedings Below .... 10

SUMMARY OF ARGUMENT ..... 12

ARGUMENT ..... 14

I. APPLICATION OF TRADITIONAL TOOLS OF STATUTORY CONSTRUCTION SHOWS THAT CONGRESS DID NOT INTEND TO PREEMPT DAMAGES CLAIMS. ..... 14

II. PREMARKET APPROVAL DOES NOT PREEMPT THE RIEGELS' DAMAGES CLAIMS. . 23

A. Premarket Approval Of Medtronic's Device Did Not Create Any Federal Requirement That Preempts The Riegels' Damages Claims. ... 24

1. The PMA Process Does Not Preempt Damages Actions. ..... 24

2. PMA Imposed No Device-Specific Design Requirements On The Device. . . . . 26

3. PMA Imposed No Device-Specific Labeling Requirements On The Device. . . . . 30

4. FDA Regulations Support A Finding Of No Preemption. . . . . 31

B. The Riegels' Claims Also Are Not Preempted Because They Are Premised On State-Law Duties Of General Applicability. . . . . 34

III. STATE REQUIREMENTS THAT PARALLEL FEDERAL REQUIREMENTS APPLICABLE TO PMA DEVICES ARE NOT PREEMPTED. . . . . 39

IV. MEDTRONIC'S POSITION WOULD IMPROPERLY FORECLOSE ALL REMEDIES FOR THE MANY PEOPLE INJURED BY PMA DEVICES. . . . 43

CONCLUSION . . . . . 46

APPENDIX

## TABLE OF AUTHORITIES

**CASES** Page

*American Airlines, Inc. v. Wolens*,
513 U.S. 219 (1995) ..... 27

*Armstrong v. Optical Radiation Corp.*,
57 Cal. Rptr. 2d 763 (Cal. Ct. App. 1996) ..... 36

*Baird v. American Medical Optics*,
693 A.2d 904 (N.J. Super. Ct. App. Div. 1997),
*modified and remanded*,
713 A.2d 1019 (N.J. 1997) ..... 36

*Bates v. Dow AgroSciences LLC*,
544 U.S. 431 (2005) ..... *passim*

*Blunt v. Medtronic, Inc.*,
2007 WL 2176136 (Wis. Ct. App. July 31, 2007) .... 27

*Bowling v. Pfizer, Inc.*,
143 F.R.D. 141 (S.D. Ohio 1992) ..... 46

*Boyle v. United Technologies Corp.*,
487 U.S. 500 (1988) ..... 28

*Callan v. G.D. Searle & Co.*,
709 F. Supp. 662 (D. Md. 1989) ..... 19

*Chisom v. Roemer*,
501 U.S. 380 (1991) ..... 18

*Christensen v. Harris*,
529 U.S. 576 (2000) ..... 34

*Cipollone v. Liggett Group, Inc.*,
505 U.S. 504 (1992) ..... 18, 28

*Commissioner v. Lundy*,
516 U.S. 235 (1996) ..... 15, 19

*Cooley v. Carter-Wallace Inc.*,
478 N.Y.S.2d 375 (N.Y. App Div. 1984) ..... 41

*Cover v. Cohen*,
461 N.E.2d 864 (N.Y. 1984) ..... 41

*Cupek v. Medtronic, Inc.*,
405 F.3d 421 (6th Cir. 2005) ..... 45

*De Buono v. NYSA-ILA Medical & Clinical Services Fund*, 520 U.S. 806 (1997) ..... 21

*Dole v. United Steelworkers of America*,
494 U.S. 26 (1990) ..... 15

*Edmonds v. Compagnie Generale Transatlantique*,
443 U.S. 256 (1979) ..... 18

*El Sheikh v. Chemical-Tainer Industries, Inc.*,
2006 WL 623464 (N.Y. Sup. Ct. Mar. 13, 2006) .... 41

*English v. General Electric Co.*,
496 U.S. 72 (1990) ..... 46

*Feiner v. Calvin Klein, Ltd.*,
549 N.Y.S.2d 692 (N.Y. App. Div. 1990) ..... 26

*Geier v. American Honda Motor Co.*,
529 U.S. 861 (2000) ..... 34

*Gonzales v. Oregon*,
546 U.S. 243 (2006) ..... 21

*Goodlin v. Medtronic, Inc.*,
167 F.3d 1367 (11th Cir. 1999) ..... 17, 21, 22, 29, 45

*Goodyear Atomic Corp. v. Miller*,
486 U.S. 174 (1988) ..... 18

*In re Guidant Corp. Implantable Defibrillators Products Liability Litigation*, MDL No. 05-1708,
2007 WL 1725289 (D. Minn. June 12, 2007) .... 44, 45

*In re Guidant Corp. Implantable Defibrillators Products Liability Litigation*, MDL No. 05-1708,
2007 WL 2071804 (D. Minn. July 16, 2007) ..... 45

*Harrison v. PPG Industries, Inc.*,
446 U.S. 578 (1980) ..... 18

*Haudrich v. Howmedica, Inc.*,
642 N.E.2d 206 (Ill. App. Ct. 1994) ..... 16

*Hawaiian Airlines, Inc. v. Norris*,
512 U.S. 246 (1994) ..... 21

*Hillsborough County v. Automated Medical Laboratories, Inc.*, 471 U.S. 707 (1985) ..... 21, 34

*Horn v. Thoratec Corp.*,
376 F.3d 163 (3d Cir. 2004) ..... 25, 36, 38, 45

*Jones v. Rath Packing Co.*,
430 U.S. 519 (1977) ..... 21

*Jones v. United States*,
526 U.S. 227 (1999) ..... 18

*Kemp v. Medtronic, Inc.*,
231 F.3d 216 (6th Cir. 2000) ..... 25

*Kernats v. Smith Industries Medical Systems*,
669 N.E.2d 1300 (Ill. App. Ct. 1996) ..... 36

*Maislin Industries v. Primary Steel, Inc.*,
497 U.S. 116 (1990) ..... 31

*Mears v. Marshall*,
944 P.2d 984 (Or. Ct. App. 1997) ..... 36

*In re Medtronic Implantable Defibrillators*,
MDL No. 1726 (D. Minn.) ..... 44

*Medtronic, Inc. v. Lohr*,
518 U.S. 470 (1996) ..... *passim*

*Michael v. Shiley, Inc.*,
46 F.3d 1316 (3d Cir. 1995) ..... 6

*Niehoff v. Surgidev*,
950 S.W.2d 816 (Ky. 1997) ..... 36

*Oja v. Howmedica*,
111 F.3d 782 (10th Cir. 1997) ..... 28, 36

*Rice v. Santa Fe Elevator Corp.*,
331 U.S. 218 (1947) ..... 21

*Silkwood v. Kerr-McGee Corp.*,
464 U.S. 51 (1984) ..... 18, 19, 21, 46

*Smith v. United States*,
508 U.S. 223 (1993) ..... 20

*Sprietsma v. Mercury Marine*,
537 U.S. 51 (2002) ..... 18, 22, 46

*In re St. Jude Silzone Heart Valve Products Liability Litigation*, MDL No. 01-1396 (D. Minn.) ..... 46

*Sullivan v. Stroop*,
496 U.S. 478 (1990) ..... 15

*In re Sulzer Hip Prosthesis and Knee Prosthesis Liability Litigation*, 268 F. Supp. 2d 907
(S.D. Ohio 2003) ..... 46

*United States v. C.R. Bard, Inc.*,
848 F. Supp. 287 (D. Mass. 1994) ..... 43

*United States v. Mead Corp.*,
533 U.S. 218 (2001) ..... 34

*Voss v. Black & Decker Manufacturing Co.*,
450 N.E.2d 204 (N.Y. 1983) ..... 40

*Walker v. Johnson & Johnson Vision Products, Inc.*,
552 N.W.2d 679 (Mich. Ct. App. 1996) ..... 36

*Webster v. Pacesetter, Inc.*,
171 F. Supp. 2d 1 (D.D.C. 2001) ..... 27

*Wisconsin Public Intervenor v. Mortier*,
501 U.S. 597 (1991) ..... 21

*Wutzke v. Schwagler*,
940 P.2d 1386 (Wash. Ct. App. 1997) ..... 36

**STATUTES**

21 U.S.C. § 321(h) ..... 1
21 U.S.C. § 321(k) ..... 31
21 U.S.C. § 321(m) ..... 31
21 U.S.C. § 331 ..... 40, 43
21 U.S.C. § 331(a) ..... 41, 42
21 U.S.C. § 332 ..... 43
21 U.S.C. § 352(a) ..... 42
21 U.S.C. § 352(j) ..... 40, 42
21 U.S.C. § 360c(a)(1)(A) ..... 3
21 U.S.C. § 360c(a)(1)(B) ..... 3
21 U.S.C. § 360c(a)(1)(C) ..... 3, 5, 40, 43
21 U.S.C. § 360c(f)(1)(A) ..... 3
21 U.S.C. § 360e(b) ..... 3
21 U.S.C. § 360e(b)(1) ..... 3, 4
21 U.S.C. § 360e(b)(1)(B) ..... 3
21 U.S.C. § 360e(d) ..... 24
21 U.S.C. § 360e(d)(2) ..... 24
21 U.S.C. § 360e(d)(2)(A) ..... 40
21 U.S.C. § 360e(d)(2)(B) ..... 40
21 U.S.C. § 360e(e) ..... 6, 40
21 U.S.C. § 360e(e)(i) ..... 41
21 U.S.C. § 360e(i) ..... 4

21 U.S.C. § 360h(d) ..... 13, 20

21 U.S.C. § 360h(e) ..... 6, 40

21 U.S.C. § 360k ..... 7

21 U.S.C. § 360k(a) ..... *passim*

21 U.S.C. § 360k(b) ..... 7, 13, 19, 20, 32

28 U.S.C. § 1254(1) ..... 1

Medical Device Amendments of 1976,
Pub. L. No. 94-295, 90 Stat. 539 (1976). ..... 2

Safe Medical Devices Act of 1990,
Pub. L. No. 101-629 (1990) ..... 4

**LEGISLATIVE MATERIALS**

H.R. Conf. Rep. No. 94-1090 (1976) ..... 2

H.R. Rep. No. 94-853 (1976) ..... 1, 2, 4, 6, 7, 16

H.R. Rep. No. 101-808 (1990),
*reprinted in* 1990 U.S.C.C.A.N. 6307 ..... 4

S. Rep. No. 94-33 (1976),
*reprinted in* 1976 U.S.C.C.A.N. 1070 ..... 2

*Food, Drugs, and Cosmetics: Hearings Before a Subcommittee of the Senate Committee on Commerce on S. 1944*, 73d Cong. (1933) ..... 46

121 Cong. Rec. S6140 (Apr. 17, 1975) ..... 2

**REGULATORY MATERIALS**

21 C.F.R. § 801.109 ..... 24, 30, 42

21 C.F.R. § 801.109(b) ..... 42

21 C.F.R. § 801.109(c) ..... 42

21 C.F.R. § 801.109(d) ..... 42

21 C.F.R. § 801.430(c) ..... 3, 30
21 C.F.R. § 801.430(d) ..... 3, 30
21 C.F.R. § 801.430(e) ..... 3, 30
21 C.F.R. Part 803 ..... 5
21 C.F.R. § 807.81(a)(3)(i) ..... 30
21 C.F.R. § 808.1 ..... 7
21 C.F.R. § 808.1(d) ..... 7, 10, 13, 32
21 C.F.R. § 808.1(d)(1) ..... 7, 36
21 C.F.R. § 808.1(d)(3) ..... 33
21 C.F.R. § 808.20 ..... 7
21 C.F.R. § 808.20(c) ..... 20
21 C.F.R. § 808.20(c)(1) ..... 32
21 C.F.R. §§ 808.53-808.101 ..... 20
21 C.F.R. Part 814 ..... 24
21 C.F.R. § 814.20 ..... 4
21 C.F.R. § 814.39 ..... 29, 30, 31, 42
21 C.F.R. § 814.39(a) ..... 5
21 C.F.R. § 814.39(d)(1) ..... 5, 31, 42
21 C.F.R. § 814.39(d)(2) ..... 5, 42
21 C.F.R. § 814.44 ..... 4
21 C.F.R. § 814.45 ..... 24
21 C.F.R. § 820.1 ..... 24
21 C.F.R. § 861.1(b)(3) ..... 5, 28
21 C.F.R. § 886.4392 ..... 28
21 C.F.R. § 1020.30(j) ..... 30

42 Fed. Reg. 30383 (1977) ..... 33

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**MISCELLANEOUS**

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## INTRODUCTION

In *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), Medtronic argued that the Medical Device Amendments of 1976 preempt all damages claims brought by injured patients against medical device manufacturers. This Court unanimously rejected that argument, which four members of the Court described as "not only unpersuasive," but "implausible." *Id.* at 487. Here, Medtronic renews its argument, now limiting it to devices that received premarket approval ("PMA") from the Food and Drug Administration ("FDA"). Under the language of the statute, the FDA's implementing regulations, and *Lohr*'s authoritative construction of 21 U.S.C. § 360k(a), however, that limitation cannot salvage Medtronic's argument. Medtronic's plea for immunity from liability for injuries caused by the most dangerous medical devices should, once again, be rejected.

## JURISDICTION

The judgment of the court of appeals was entered on May 16, 2006. Pet. App. 1a. The petition for a writ of certiorari was filed on August 3, 2006, and was granted on June 25, 2007. This Court has jurisdiction under 28 U.S.C. § 1254(1).

## STATUTES AND REGULATIONS INVOLVED

The principal statutory and regulatory provisions involved in this case are reproduced in the appendix to this brief.

## STATEMENT OF THE CASE

Under federal law, the term "medical device" includes a wide array of products, ranging from common household items such as bandages and toothbrushes, to prosthetic devices such as hip and knee replacements, to cardiac devices such as artificial heart valves and pacemakers. *See* 21 U.S.C. § 321(h). Before 1976, medical devices were largely unregulated. Although for many years the FDA had authority to allow or prevent the entry of new drugs onto the market, the agency lacked such authority over medical devices. *See* H.R. Rep. No.

94-853, at 8-10 (1976); *id.* at 11 (a "serious drawback of the existing authority is that FDA cannot act against a hazardous medical device until after it is on the market"). As a result, the FDA was expending significant resources to seize or enjoin marketing of dangerous devices that never should have been marketed in the first place. *Id.* at 7-8.

By the mid-1970s, the dangers of this regulatory gap were made clear by a series of public health hazards caused by medical devices. Most notably, the defectively designed Dalkon Shield intrauterine device, which had entered the market without prior regulatory scrutiny, had caused many deaths and thousands of serious injuries. *See id.* at 8; S. Rep. No. 94-33, at 1-2, 6-7 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1070-72, 1075-76. The House and Senate reports also recount the hundreds of deaths and injuries caused by heart valves and pacemakers, and severe eye injuries caused by intraocular lenses. H.R. Rep. No. 94-853, at 9; S. Rep. No. 94-33, at 6.

**A. The Medical Device Amendments**

In response to the harm caused by medical devices, Congress enacted the Medical Device Amendments of 1976 ("MDA") to the Food, Drug, and Cosmetic Act ("FDCA"). Pub. L. No. 94-295, 90 Stat. 539 (1976) (chiefly codified at 21 U.S.C. § 360c *et seq.*). The primary purpose of the new law was "to protect the public health" by preventing the distribution of dangerous devices. *See* H.R. Conf. Rep. No. 94-1090, at 1 (1976); H.R. Rep. No. 94-853, at 6-12. Introducing the MDA on the Senate floor, the bill's principal sponsor, Senator Edward Kennedy, stated: "The legislation is written so that the benefit of the doubt is always given to the consumer. After all, it is the consumer who pays with his health and his life for medical device malfunctions." 121 Cong. Rec. S6140 (Apr. 17, 1975).

Under the MDA, each medical device falls into one of three classes. Class I devices, such as bandages, are the least risky devices and are subject only to "general controls" applicable to

all devices, such as general labeling requirements and good manufacturing practices rules promulgated by the FDA. *See* 21 U.S.C. § 360c(a)(1)(A).

Class II devices, such as hearing aids and tampons, are more likely than class I devices to cause harm if they are defective or misused. *Id.* § 360c(a)(1)(B). The FDA may promulgate regulations subjecting them to "special controls," such as the agency's specific absorbency testing requirements for tampons and specific warning language for tampon labeling. *See* 21 C.F.R. § 801.430(c), (d) & (e).

Class III devices—such as the devices at issue here and in *Lohr*—include life-supporting or life-sustaining devices and devices that pose the greatest risk of serious injury. 21 U.S.C. § 360c(a)(1)(C). In general, class III devices cannot be marketed until the FDA has found a "reasonable assurance" that they are safe and effective. *Id.* Marketing permission granted through this process is called premarket approval, or PMA. *Id.* § 360e(b)(1).

With respect to class III devices already on the market in 1976 when the statute was enacted, the MDA did not require immediate PMA. Rather, such a device can be marketed without PMA until the FDA issues a regulation calling for PMA for that type of device. *Id.* § 360e(b). Likewise, if the FDA finds that a class III device is "substantially equivalent" to a device marketed prior to the MDA's effective date (or to a device that itself was found to be "substantially equivalent" to a pre-MDA device), that device need not obtain PMA until the FDA issues a regulation requiring PMA for that type of device. *Id.* §§ 360e(b)(1)(B), 360c(f)(1)(A). The process for giving marketing approval to substantially equivalent devices is sometimes referred to as the "510(k)" process, after the section of the FDCA under which the marketing request is submitted.

Although devices marketed prior to enactment of the MDA are sometimes referred to as having been "grandfathered," the MDA *requires* the FDA to issue regulations calling for PMA

for these older class III devices. *Id.* § 360e(b)(1) ("[T]he Secretary *shall* by regulation . . . require that such device have an approval . . . .") (emphasis added); H.R. Rep. No. 94-853, at 31 ("The requirement to have an approved application for premarket approval with respect to these 'old' devices is subject to provisions delaying the requirement for a statutory period."). Thus, the MDA demands that all class III devices eventually be PMA devices—that is, that no class III devices will be marketed without FDA approval. Because after 14 years the FDA still had not called for PMA for many pre-1976 class III devices, Congress reiterated this requirement in 1990 amendments to the MDA. *See* H.R. Rep. No. 101-808, at 26 (1990), *reprinted in* 1990 U.S.C.C.A.N. 6307, 6319 ("The Committee has serious concerns about FDA's failure to issue regulations under section 515(b) calling for submission of safety and effectiveness data on the great majority of pre-Amendment class III devices and their post-Amendment substantial equivalents.").[1]

Significantly, the FDA does not design PMA devices or draft the labeling, and it does not test or conduct studies of devices. Rather, a device's design and labeling originate with the manufacturer, on whose data the FDA depends when it reviews the PMA application. *See* 21 C.F.R. §§ 814.20, 814.44.

When granting PMA, the FDA typically sends the manufacturer a form approval letter reminding the manufacturer of generally applicable obligations under federal

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[1]The Safe Medical Devices Act of 1990, Pub. L. No. 101-629 (1990) ("SMDA"), required the FDA to issue, before December 1, 1995, a regulation for each grandfathered or 510(k) device, either designating the device as a class I or class II device, or requiring the device to remain in class III. For each device that remained in class III, the SMDA required the FDA to call for PMA applications within 12 months of the regulation requiring that the device remain in class III. 21 U.S.C. § 360e(i). The FDA did not meet these deadlines.

regulations. *See, e.g.*, JA 9. Little in the form letter is device-specific. The FDA may establish specific performance standards as a condition of granting PMA, 21 C.F.R. § 861.1(b)(3), but it rarely does so. And although manufacturers of PMA devices must generally conform their products to the approved design and labeling that they devised, they may make design changes with FDA approval by submitting a "PMA supplement." *Id.* § 814.39(a). They may also make labeling changes to enhance safety, such as strengthening contraindications and warnings, even before obtaining approval from the FDA. *Id.* §§ 814.39(d)(1) & (2).

If the FDA finds that a PMA application satisfies the "reasonable assurance" standard, 21 U.S.C. § 360c(a)(1)(C), the FDA will grant PMA even if a better, safer product is already on the market. In addition, once approved, a device can be marketed indefinitely. That is, PMAs do not expire, and there is no periodic review process. The MDA calls for manufacturers and user facilities (such as hospitals) to submit to the FDA reports of adverse events associated with their devices. 21 C.F.R. Part 803. However, the "FDA does not systematically act to ensure that the reported problems receive prompt attention and appropriate resolution. As a result, FDA's adverse event reporting system is not providing an early warning about problem medical devices." GAO, *Medical Device Reporting: Improvements Needed in FDA's System for Monitoring Problems With Approved Devices* 2 (Jan. 1997), *available at* www.fda.gov/cdrh/hes9721.pdf. The FDA itself has characterized its post-marketing surveillance system for medical devices as "not working well." FDA, *FY 2004 Annual Performance Plan* 2.6.1 (Jan. 2003), www.fda.gov/ope/fy04plan/2004pp-cdrh.html.

"No amount of rigour in the pre-marketing review process can predict all possible device failures or incidents arising from device misuse. It is through actual use that unforeseen problems related to safety and performance can occur." World Health Organization, *Medical Device Regulations: Global*

*Overview and Guiding Principles* 13 (2003), *available at* www.who.int/medical_devices/publications/en/MD_Regulations.pdf. In recognition of this reality, the MDA gives the FDA authority to withdraw approval and, pursuant to amendments passed in 1992, to recall devices. 21 U.S.C. §§ 360e(c), 360h(e). However, the FDA rarely, if ever, invokes this authority, preferring instead to rely on market forces, the tort system, or the threat of agency action to prompt voluntary recalls. *See* FDA, *Learn About Medical Devices* (Dec. 19, 2005), www.fda.gov/cdrh/recalls/learn.html#2 ("Legally, FDA can require a company to recall a device. This could happen if a company refuses to recall a device that is associated with significant health problems or death. However, in practice, FDA has rarely needed to require a medical device recall.").[2]

### B. State Regulatory Activity And Preemption Under The MDA

When drafting the MDA, Congress was informed of state regulatory programs that had stepped into the federal regulatory vacuum. Most notably, a California statute required that medical devices undergo premarket approval before commercial distribution in the state and that they comply with state good manufacturing practices regulations. *See* H.R. Rep.

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[2]*See, e.g.*, Boston Scientific, *Boston Scientific to Recall Additional Coronary Stent Systems*, July 16, 2004, *available at* www.fda.gov/cdrh/recalls/recall-071604-pressrelease.html (voluntary recall due to design defect in PMA balloon catheter); St. Jude Medical, *Silzone Coating Advisory* (2007), www.sjm.com/devices/silzoneadvisory.aspx?name=SJM+Regent%26%23174%3B+Valve&location=in&type=18&section=overview (January 2000 voluntary recall of defective PMA heart valve replacement and repair products that used Silzone coating); *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1320-21 (3d Cir. 1995) (company voluntarily recalled PMA heart valve, several years after device started to fracture and cause patient death; FDA withdrew approval only after company requested that it do so).

No. 94-853, at 45. To prevent a "substantial number of differing requirements applicable to a medical device," *id.*, Congress crafted a provision, 21 U.S.C. § 360k, to address such state regulatory programs.

Section 360k has two parts. Section 360k(a) preempts certain state-law "requirements" "with respect to a device" that are "different from, or in addition to," MDA "requirements." *See infra* 1a. Under § 360k(b), the FDA may exempt from preemption state requirements that would otherwise be preempted. *Id.*

FDA regulations implementing § 360k(b) reflect the narrow reach of § 360k(a). *See* 21 C.F.R. §§ 808.1, 808.20, *reprinted infra* 3a-8a; *see Lohr*, 518 U.S. at 498 n.18 ("FDA's narrow understanding of the scope of § 360k(a) is obvious from the full text of the regulation . . . ."). The regulations state, in part:

> State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements.

21 C.F.R. § 808.1(d). In addition, under the regulations' reading of § 360k(a), preemption does not extend to a state requirement of "general applicability where the purpose of the requirement relates . . . to other products in addition to devices." *Id.* § 808.1(d)(1).

More than 10 years after enactment of the MDA, device manufacturers began to argue that § 360k(a) expressly preempts state-law damages actions. The legislative history of § 360k(a), however, refers solely to the potential for preemption of state and local laws and regulations. *See* H.R. Rep. No. 94-853, at 4, 45-46. Damages actions are mentioned elsewhere in the

legislative record to show the extent of the harm caused by the Dalkon Shield, and without any suggestion that Congress was concerned about the lawsuits themselves. *Id.* at 8.

### C. The Decision In *Medtronic v. Lohr*

In *Medtronic, Inc. v. Lohr*, Lora Lohr and her husband Michael Lohr filed suit under Florida law for damages resulting from an allegedly defective class III pacemaker lead that the FDA had cleared for marketing under its § 510(k) "substantial equivalence" process. This Court held that none of the Lohrs' state-law damages claims—based on defective design, defective manufacture, and failure to warn—was preempted by the MDA.

**1.** *The Majority Opinion.* All members of the Court concurred in three holdings of the *Lohr* majority opinion: (1) The MDA does not broadly preempt all state-law damages claims against device manufacturers, *see* 518 U.S. at 480 (majority); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part); (2) the Lohrs' design-defect claim was not preempted because the FDA had not issued any design specifications for the device in question, *id.* at 492-94 (majority); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part); and (3) a tort claim premised on state-law duties "equal to, or substantially identical to, requirements" imposed by the MDA, or FDA regulations implementing the MDA, is not preempted. *Id.* at 494-97 (majority); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part).

By a 5-4 margin, in Part V of the *Lohr* majority opinion, the Court also held that the Lohrs' failure-to-warn and manufacturing-defect claims were not preempted, even if they did more than seek to enforce federal standards. The Court looked to the language of the MDA's preemption provision and the FDA's preemption regulations and noted the "overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." *Id.* at 500. The generality of the federal labeling and

manufacturing regulations applicable to the pacemaker lead, the Court held, precluded a finding of preemption. Those regulations, the Court said, reflect "important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation which the statute or regulations were designed to protect from potentially contradictory state requirements." *Id.* at 501.

The Court further explained in Part V that the Lohrs' damages claims were premised on general state-law duties that did not focus specifically on medical devices, and that they were not preempted for that reason as well. The Court found that general state-law duties to use due care in manufacturing and to warn users of potential risks are not the types of "requirements" that Congress or the FDA feared would impede the FDA's ability to enforce specific federal laws and regulations. Therefore, the majority held, claims based on these duties are outside the prohibited category of state-law requirements "with respect to" specific devices within the meaning of § 360k(a). *Id.* at 501-02.

In addition, speaking for a four-Justice plurality, Parts IV and VI of the lead opinion relied on the MDA's language and history to conclude that § 360k(a) was not intended to preempt most, and perhaps any, damages claims. *Id.* at 488-91. The plurality found it unnecessary to decide whether § 360k(a) reached any damages claims, however, because, under the majority's analysis, none of the Lohrs' claims was preempted. *Id.* at 502-03.

**2.** *The Concurrence.* Justice Breyer filed a concurring opinion stating that, in his view, § 360k(a)'s reference to state-law "requirements" encompasses some state-law damages claims. He did not join Parts IV and VI of the lead opinion because he was not convinced that MDA preemption of damages claims would be "rare." *Id.* at 508. He joined fully, however, in Part V of the majority opinion, which demanded

specificity on both the state and federal sides of § 360k(a)'s preemption analysis. He looked to the FDA's preemption regulation, 21 C.F.R. § 808.1(d), which amplifies the meaning of § 360k(a), and stated that, "[i]nsofar as there [were] any applicable FDA requirements" at issue, they were not "'specific' in any relevant sense." 518 U.S. at 505-07. He stated that the language of § 360k(a) reflects principles of conflict preemption, but found no conflict between any federal requirement and any of the Lohrs' claims. *Id.* at 506.

**3.** *The Partial Dissent.* Justice O'Connor concurred in part and dissented in part, joined by Chief Justice Rehnquist and Justices Scalia and Thomas. In her view, state-law damages claims could constitute "requirements" under § 360k(a). *Id.* at 509-11. Although concurring with the majority that the Lohrs' design-defect claim was not preempted, she would have held that the manufacturing-defect and failure-to-warn claims were preempted in part because, in her view, they sought to impose "requirements" different from those imposed by the FDA's manufacturing and labeling rules. *Id.* at 513-14. She agreed with the majority, however, that the failure-to-warn and manufacturing-defect claims were not preempted to the extent that they alleged violations of federal requirements. *Id.* at 513.

### D. Factual Background And Proceedings Below

This action arose from serious injuries caused by a defective Medtronic percutaneous transluminal coronary angioplasty ("PTCA") catheter. The model at issue received marketing approval in 1994 as a supplement to a PMA first issued in 1988. In 1995 and 1996, Medtronic sought and received approval to make design and labeling changes. Medtronic no longer manufactures the product.

In May 1996, Charles Riegel underwent an angioplasty intended to dilate his coronary artery. His physician used the Medtronic catheter, which burst during the angioplasty. Mr. Riegel developed a complete heart block and lost conscious-

ness and blood pressure. He needed advanced life support and emergency coronary bypass surgery. Pet. App. 4a.

The Riegels sued Medtronic, alleging design and manufacturing defects and inadequate warning, and stating negligence, strict liability, breach of warranty, and loss of consortium claims. The design-defect claim alleges that the product was not designed adequately to function as intended and was unreasonably dangerous. The inadequate warning claim focuses on conflicting information on the label, which, on the one hand, stated not to inflate the catheter's balloon above 8 atmospheres of pressure but, on the other hand, showed test results for inflation up to 13 atmospheres, implying that inflation above 8 atmospheres was acceptable.

In January 2002, Medtronic moved for summary judgment based on preemption and to dismiss the express warranty claim for failure to state a claim. In March 2002, the district court granted the summary judgment motion in part, holding that the negligent manufacturing and express warranty claims could go forward. *See id.* at 55a. Following discovery, Medtronic moved for summary judgment on the two remaining claims, and the court granted the motion. *Id.* at 75a.

The Riegels appealed the district court's decisions with respect to preemption and dismissal of the negligent manufacturing claim. In a 2-to-1 decision, the Second Circuit affirmed the district court. The majority held that PMA imposes device-specific preemptive "requirements" within the meaning of § 360k(a) and that state-law design-defect and inadequate warning claims are sufficiently "device-specific" to warrant preemption. *Id.* at 25a, 32a-33a. The majority suggested that jury verdicts put manufacturers of PMA devices in an untenable position because compliance with both federal requirements and the standards represented by jury verdicts might be "impossible." *Id.* at 34a. The court did not attempt to reconcile that statement with the decades of product liability litigation against device manufacturers or with this Court's recent

decision in *Bates v. Dow AgroSciences LLC*, which noted that "an event, such as a jury verdict, that merely motivates an optional decision is not a requirement." 544 U.S. 431, 445 (2005).[3]

Judge Pooler dissented from the panel's preemption decision. Explaining that express preemption is a question of congressional intent, she noted the complete lack of evidence that Congress intended to preempt damages claims. Pet. App. 46a. She further observed that the idea that damages claims are "unambiguously preempted is 'particularly dubious' considering that it appears that until relatively recently neither the industry nor the FDA thought that such claims were preempted." *Id.* at 46a (citing *Bates*, 544 U.S. at 449). Judge Pooler explained that the majority opinion overlooked "two critical aspects of the preemption analysis: the presumption against preemption and congressional intent." *Id.* at 43a. She also observed that "the lack of any device-specific federal requirement [for PTCA catheters] makes it impossible" to conduct "a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations." *Id.* at 50a (quoting *Lohr*, 518 U.S. at 500).

## SUMMARY OF ARGUMENT

**1.** Application of the traditional tools of statutory construction demonstrates § 360k(a)'s narrow reach. The language of § 360k(a) does not naturally include state-law damages claims within its preemptive scope. And when Congress enacted the MDA, it said nothing about preempting damages claims. Given the controversial nature of such preemption, Congress's silence

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[3]The Second Circuit also affirmed the holding of the district court dismissing the negligent manufacturing claim on the merits. Pet. App. 43a. That issue is not before the Court.

cannot reasonably be seen as an expression of intent to preempt such claims.

Moreover, Congress included in the MDA two provisions that confirm that § 360k(a) does not preempt damages claims. Section 360k(b), which allows the FDA to exempt state "requirements" from preemption, cannot workably be applied to damages claims. And § 360h(d), entitled "Effect on Other Liability," reveals that, in enacting the MDA, Congress expected that state-law claims would proceed against device manufacturers. The decision below runs contrary to that expectation and should be rejected.

This Court has time and again relied on the presumption that a federal statute may not be construed to preempt the historic police powers of the states absent a finding of Congress's "clear and manifest" intent to do so. The language of § 360k(a) displays no such unambiguous intent. In fact, device manufacturers themselves did not even conceive of the argument that § 360k(a) preempts damages claims until more than a decade after the MDA's enactment.

**2.** In *Lohr*, the Supreme Court rejected Medtronic's attempt to immunize itself from tort liability in a context similar to this one. Like this case, *Lohr* involved an injury caused by a defective class III medical device. As in this case, Medtronic argued that the MDA preempted the plaintiffs' state-law damages claims. This Court's majority opinion rejected Medtronic's argument. Relying on the language of § 360k(a) and the FDA's longstanding regulation, 21 C.F.R. § 808.1(d), the Court held that for the MDA to preempt a state-law claim, that claim must correspond to some device-specific federal requirement and the state law must have been developed "with respect to" devices. Neither the federal nor the state side of that holding is satisfied here because the PMA process does not impose device-specific design or labeling requirements, and neither a damages verdict nor the common-law duties that

would underlie such a verdict represent device-specific state-law requirements.

**3.** The Court in *Lohr* unanimously agreed that state-law claims that seek to enforce duties substantially identical to federal requirements are not preempted. That holding applies fully here and compels a finding that the Riegels' claims are not preempted. Even assuming that there are federal requirements applicable to the device within the meaning of § 360k(a), the design defect and inadequate warning claims are based on duties equivalent to the federal standards.

**4.** The court of appeals erroneously assumed that the effect of its decision finding preemption of state-law damages remedies for people injured by PMA devices was "quite limited." Pet. App. 36a. In fact, PMA devices, which are the riskiest devices, injure a great many patients. Thus, the effect of holding that § 360k(a) preempts damages claims based on injuries caused by PMA devices would not be "quite limited," but quite broad. Federal law provides no alternative remedy for these patients, which, in light of the presumption against pre-emption, further supports a narrow construction of § 360k(a).

## ARGUMENT

Medtronic maintains, and the court below held, that because the FDA approved its catheter for marketing, it is entitled to immunity from state-law damages suits, regardless of their merits, the nature of Medtronic's conduct, or the severity of the resulting injuries. Medtronic's position is contradicted by the purpose and language of the MDA and by this Court's preemption jurisprudence.

### I. APPLICATION OF TRADITIONAL TOOLS OF STATUTORY CONSTRUCTION SHOWS THAT CONGRESS DID NOT INTEND TO PREEMPT DAMAGES CLAIMS.

The language of § 360k(a)—preempting state "requirements" "with respect to a device" that are "different from or in

addition to" federal requirements—shows that Congress did not intend the MDA to preempt state damages actions. Section 360k(a) refers once to state-law "requirements" that are candidates for preemption and twice to federal "requirements" that may have preemptive effect. *See infra* 1a. The federal "requirements" flow solely from positive law—the MDA and its regulations. To interpret state-law "requirements" as including actions for damages would thus run counter to the basic rule of statutory construction that multiple uses of the same word in the same statute should be accorded the same meaning. *Commissioner v. Lundy*, 516 U.S. 235, 250 (1996); *Sullivan v. Stroop*, 496 U.S. 478, 484 (1990). In addition, § 360k(a) preempts only state-law requirements "with respect to a device." Unlike state statutory or regulatory requirements for devices, general common-law duties are not requirements "with respect to a device." And if the Riegels prevail at trial, Medtronic will be obligated only to pay damages; it will not be required to do anything with "respect to [the] device." *See Bates*, 544 U.S. at 445.

The starting point for discerning Congress's intent is the text of § 360k(a). *Lohr*, 518 U.S. at 484.[4] But in construing that text, the Court is "not guided by a single sentence or member of a sentence, but look[s] to the provisions of the whole law, and to its object and policy." *Dole v. United Steelworkers of Am.*, 494 U.S. 26, 35 (1990) (citations and internal quotation marks omitted). Like the language of § 360k(a) itself, these traditional tools of statutory construction show that Congress did not intend § 360k(a) to preempt damages claims at all and that, if § 360k(a) is nonetheless read

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[4]The part of the *Lohr* opinion quoted above and all other aspects of *Lohr* relied on in this Argument are from the majority opinion, unless otherwise stated.

to encompass damages claims, such preemption would occur only in very narrow circumstances.[5]

**A.** If Congress had intended to take the significant and controversial step of preempting state-law damages claims for patients injured by the most dangerous medical devices (those that require PMA), one would expect a great deal of discussion and debate about that proposal. Yet "the debate and Congressional record are barren of any indication that Congress intended to preempt court decisions by passing" the MDA. *Haudrich v. Howmedica, Inc.*, 642 N.E.2d 206, 211 (Ill. App. Ct. 1994). Instead, "[a]ny fair reading of the legislative history of the [MDA] will reveal that, except for a few passing references to the need to avoid slowing innovations in medical technology, the critical, and endlessly repeated, focus of congressional attention was to protect consumers from dangerous devices." R. Adler & R. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 922 n.126 (1994) (citation omitted).

Although silent with respect to damages claims, the legislative record is clear that the impetus for Congress's enactment of a preemption provision was the existence of state regulatory programs that potentially could subject device manufacturers to inconsistent requirements once federal requirements were put into place. Addressing the purpose of § 360k(a), the House Report explained: "In the absence of effective federal regulation of medical devices, some States have established their own programs," the most comprehensive of which was California's law requiring premarket approval of new devices and compliance with the state's good manufacturing practices regulations. H.R. Rep. No. 94-853, at

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[5]The majority holding in *Lohr* does not resolve the question whether damages claims can ever be considered "requirements" under § 360k(a). As in *Lohr*, the Court may, but need not, decide this question to hold that the damages claims here are not preempted. *See infra* parts II-III.

45. In contrast to such regulatory schemes, damages claims are not state "programs" "established" in reaction to the "absence of effective federal regulation" of devices. Such claims existed (and exist) apart from federal and state regulation, having developed as part of traditional state tort laws.

Congress's silence on preemption of damages actions is particularly telling because the MDA was motivated by the "increasingly severe injuries that resulted from the failure" of medical devices, particularly the Dalkon Shield intrauterine device. *Lohr*, 518 U.S. at 476. Congress was "acutely aware of ongoing product liability litigation" regarding these incidents, *id.* at 491 (plurality opinion), which makes "its failure even to hint at [preemption of traditional common-law remedies] . . . spectacularly odd." *Id.* The legislative history reveals that Congress focused on "regulat[ing] medical devices *before* they reached consumers, rather than on addressing their consequences once on the market." *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1378 (11th Cir. 1999). The congressional reports and hearings on the MDA show, not simply that Congress "did not focus specifically upon the matter" of preempting damages claims, *Lohr*, 518 U.S. at 504 (Breyer, J., concurring), but that Congress had no concern about ongoing tort suits against device manufacturers.

Moreover, although *Lohr* holds that § 360k(a) does not preempt damages claims brought in connection with 510(k) devices, the MDA requires the FDA eventually to call for PMA for all class III devices. *See supra* pp. 3-4; *Lohr*, 518 U.S. at 479 ("Congress anticipated that the FDA would complete the PMA process for Class III devices relatively swiftly."). Accordingly, to find preemption here would be to conclude that Congress intended to preempt damages claims for *all* class III devices—without a word of discussion.

The conclusion that § 360k(a) was not intended to preempt damages claims is consistent with this Court's decisions recognizing that Congress can, and does, rationally distinguish

state positive law and common law, preempting the former but not the latter. As the Court stated in *Sprietsma v. Mercury Marine*, preemption of state positive law, but not state common law "does not produce anomalous results. It would have been perfectly rational for Congress not to pre-empt common-law claims, which—unlike most administrative and legislative regulations—necessarily perform an important remedial role in compensating accident victims." 537 U.S. 51, 64 (2002) (citing *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984)); *see Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 518 (1992) ("[T]here is no general, inherent conflict between [express] federal preemption of state [regulatory] warning requirements and the continued vitality of state common-law damages actions."); *Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185-86 (1988) ("The effects of direct regulation . . . are significantly more intrusive than the incidental effects of such an award provision. . . . Congress may reasonably determine that incidental regulatory pressure is acceptable, whereas direct regulatory authority is not.").

In 1976, for Congress to have preempted damages claims without providing an alternative means of compensation would have been unprecedented. Yet "Congress is unlikely to intend any radical departures from past practice without making a point of saying so." *Jones v. United States*, 526 U.S. 227, 234 (1999); *accord Edmonds v. Compagnie Generale Transatlantique*, 443 U.S. 256, 266-67 (1979) (rejecting interpretation of statute that would modify longshoremen's pre-existing rights against negligent vessels where reports and debates leading up to enactment "contain not a word of this concept"). For this reason, "[i]n a case where the construction of legislative language such as this makes so sweeping and so relatively unorthodox a change as that made here, . . . judges . . . may take into consideration the fact that a watchdog did not bark in the night." *Harrison v. PPG Indus., Inc.*, 446 U.S. 578, 602 (1980) (Rehnquist, J., dissenting); *see Chisom v. Roemer*, 501 U.S. 380, 396 (1991) (rejecting proffered statutory construction

because "if Congress had such an intent, Congress would have made it explicit in the statute, or at least some of the Members would have identified or mentioned it at some point in the unusually extensive legislative history").

The glaring absence in the legislative record of any suggestion that consumers would lose their only means of obtaining compensation for injuries caused by poorly designed or inadequately labeled PMA devices counsels against a finding of preemption. "Congress would [not], without comment, remove all means of judicial recourse for those injured by illegal conduct." *Silkwood*, 464 U.S. at 251.

**B.** Reading § 360k(a) in context reinforces that it does not apply to common-law claims. Section 360k includes not only the preemption provision but also subsection (b), which addresses exemptions from preemption. Subsection (b) authorizes the FDA to exempt a state "requirement" from preemption "[u]pon application of a State or a political subdivision thereof," if the state requirement is "more stringent than a requirement" under the MDA, is "required by compelling local conditions," and would not cause the device to be in violation of any MDA requirement. *See infra* 1a.

In accordance with standard rules of statutory construction, "requirement" should be read to have the same meaning in subsection (a) as in subsection (b). *Commissioner v. Lundy*, 516 U.S. at 250. Yet it is implausible that "requirement" in subsection (b) includes damages claims. A state seeking a blanket exemption for its common law could not show that the law was more stringent than MDA requirements because the common law is typically stated in very general terms. *See, e.g.*, *infra* p. 41 (describing New York law). And reading § 360k(b) to create a system in which states petitioned the FDA for exemptions *after* each verdict in favor of a plaintiff would be "absurd." *Callan v. G.D. Searle & Co.*, 709 F. Supp. 662, 667 (D. Md. 1989). Not surprisingly, the FDA has interpreted "requirement" in § 360k(b) to apply to a "statute, rule,

regulation, or ordinance," not to common law. *See* 21 C.F.R. § 808.20(c). States have construed it similarly, as they apparently have not applied for exemptions for common-law claims. *See* 21 C.F.R. §§ 808.53-808.101.

Section 360k(b) distinguishes the MDA's preemption provision from the preemption provisions at issue in *Cipollone* and *Bates*. Neither of the statutes at issue in those cases contains a subsection, comparable to § 360k(b), that works in tandem with the preemption provision and thus provides an additional aid to discerning the scope of the preemption intended by Congress. "Language, of course, cannot be interpreted apart from context." *Smith v. United States*, 508 U.S. 223, 229 (1993). In the MDA, reading "requirement" in § 360k(a) together with that same term in § 360k(b) confirms that Congress did not intend that preempted "requirements" would include state common law.

In addition, the MDA refers directly to liability under state law in only one provision, 21 U.S.C. § 360h(d), and that provision indicates that Congress expected that damages actions against device manufacturers would continue after enactment of the MDA. Under § 360h, the FDA has the power to notify health professionals and the public of unreasonable risks associated with devices and to order device manufacturers to repair, replace, or provide refunds and reimbursements with respect to devices that pose such risks. Subsection (d) of § 360h, entitled "Effect on Other Liability," provides:

> Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

Thus, "the only congressional discussion concerning the relationship between the [statute] and state tort remedies

indicates that Congress assumed that such remedies would be available." *Silkwood*, 464 U.S. at 251 (holding no preemption of punitive damages claim under Atomic Energy Act); *see Goodlin*, 167 F.3d at 1379 ("[T]he savings clause [§ 360h(d)] casts real doubt on the idea that Congress intended to preempt state tort liability for all PMA approved devices.").

**C.** In addition to the statute's text, purpose, and legislative history, interpretation of § 360k(a) is informed by the well-established presumption against preemption. *Lohr*, 518 U.S. at 485. This strong presumption buttresses the conclusion that § 360k(a) does not preempt state-law damages claims at all (or, at most, that it does so only in narrow circumstances). As the Court has reiterated, "the regulation of health and safety matters is primarily, and historically, a matter of local concern." *Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 716, 719 (1985); *see Gonzales v. Oregon*, 546 U.S. 243, 126 S. Ct. 904, 923 (2006); *Lohr*, 518 U.S. at 485. The presumption against preemption instructs that the historic police powers of the states are not superseded by federal law "unless that was the clear and manifest purpose of Congress." *De Buono v. NYSA-ILA Med. & Clinical Servs. Fund*, 520 U.S. 806, 814 n.8 (1997) (citation and internal quotation marks omitted); *see Bates*, 544 U.S. at 449; *Lohr*, 518 U.S. at 485; *Hawaiian Airlines, Inc. v. Norris*, 512 U.S. 246, 252 (1994); *Wisconsin Pub. Intervenor v. Mortier*, 501 U.S. 597, 605, 611 (1991); *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). This approach "provides assurance that the 'federal-state balance' will not be disturbed unintentionally by Congress or unnecessarily by the courts." *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977) (citation omitted). The presumption applies where a defendant is seeking preemption of state tort remedies for bodily injury because, in that situation, preemption would displace the historic power of the states to protect the health and safety of their citizens. *See, e.g., Lohr*, 518 U.S. at 484-86.

Here, § 360k(a)'s plain language preempts only state-law "requirements." Although this Court has held that the word "requirements" *may* include damages claims, *see Bates*, 544 U.S. at 443, as used in § 360k(a), the word certainly does not manifest an unambiguous intent do so. *See* P. Hutt, R. Merrill, & L. Grossman, *The Ambiguous Medical Device Amendments, in Food and Drug Law* 1439 (3d ed. 2007) (heading in chapter entitled "Statutory Preemption"); *see also Sprietsma*, 537 U.S. at 63 (statute providing that states "may not establish, continue in effect, or enforce a law or regulation . . . imposing a requirement" does not preempt common-law claims). And in 1976, when Congress drafted the MDA, the Court had not yet recognized that, when used in a preemption provision, the term might refer to a damages claim. *Cf. Bates*, 544 U.S. at 441 (noting "groundswell" of cases about express preemption under 1972 provision of Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") after *Cipollone* was decided in 1992).[6] In 1976, the Court had also never found tort pre-emption in the absence of a federal remedy. In light of the legislative record and the presumption against preemption, even if Medtronic's reading were plausible—indeed, even if it were just as plausible as the Riegels'—the Court "would nevertheless have a duty to accept the reading that disfavors pre-emption." *Bates*, 544 U.S. at 449.

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[6]Similar to the situation described in *Bates*, "the first reported decisions on the industry's attempts to assert federal preemption of state product liability claims for devices subject to the FDA's approval regimes did not appear until 1991, fifteen years after Congress passed the MDA." *Goodlin*, 167 F.3d at 1381; *see* Pet. App. 46a-47a. The notion "that the industry would have ignored its immunity under the MDA for so long after the statute's enactment if Congress, in fact, had intended to provide immunity in 1976" is far-fetched. *Id.*

Because the language of § 360k(a), read in conjunction with the statute's purpose, the legislative history, and the MDA as a whole, does not manifest an intent to preempt damages claims, the decision below should be reversed.

## II. PREMARKET APPROVAL DOES NOT PREEMPT THE RIEGELS' DAMAGES CLAIMS.

The majority opinion in *Lohr*, while not excluding the possibility that § 360k(a) might preempt some damages claims, adopts a narrow construction of the provision that reflects both the presumption against preemption and the apparent absence of congressional intent to eliminate damages claims against device manufacturers. *Lohr*'s construction of § 360k(a) confirms the conclusion required by the MDA's purpose and the history of device regulation: PMA does not preempt state design-defect and failure-to-w[redacted]s.

In holding that § 360k(a) did not preempt the damages claims at issue in *Lohr*, this Court noted that both the statutory language and FDA regulations reveal an "overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." 518 U.S. at 500. The statute and regulations, the Court held, "require a careful comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope of the statute and regulations." *Id.* Although *Lohr* involved a device marketed pursuant to a finding of substantial equivalence under § 510(k), the Court's construction of § 360k(a) yields the same result when applied to cases involving PMA devices. Medtronic's catheter was not subject to a device-specific federal requirement, and the Riegels' damages claims would not impose on the catheter a device-specific state requirement. For each of these reasons, § 360k(a) does not preempt the claims alleged here.

### A. Premarket Approval Of Medtronic's Device Did Not Create Any Federal Requirement That Preempts The Riegels' Damages Claims.

#### 1. The PMA Process Does Not Preempt Damages Actions.

Device manufacturers have argued both that the rigor of FDA review makes the PMA process itself a requirement that preempts damages claims, and that the granting of PMA imposes requirements that preempt damages claims. Neither is correct. PMA signifies that the FDA has examined the manufacturer's application and determined that the device satisfies federal criteria for marketing. *See* 21 U.S.C. § 360e(d). The federal criteria for PMAs are generally applicable threshold standards set out in the MDA and the FDA's implementing regulations. *See* 21 C.F.R. § 814.45 (grounds for denying a PMA). The manufacturer is responsible for submitting an application demonstrating that the proposed medical device satisfies those minimum standards. *See, e.g., id.* Part 814. Where, as here, the FDA has not set out specific federal requirements for the particular device, the manufacturer may select any design and labeling features that will satisfy the general minimum standards of the MDA and FDA regulations. *See generally supra* pp. 4-5.

Thus, although a PMA application and the FDA's scrutiny of it are more extensive than in the case of a 510(k) device, such as the device at issue in *Lohr*, *see* 518 U.S. at 479 (explaining differences), the approval criteria for PMA are no more "specific" than for the 510(k) process. Both processes apply to class III devices generally, *id.*, and neither specifies how a product is to be designed, labeled, or manufactured. The same labeling regulations, 21 C.F.R. § 801.109, and good manufacturing practices regulations, *id.* § 820.1, apply to both PMA and 510(k) devices. The PMA process demands that all PMA devices provide a "reasonable assurance" of safety and effectiveness, 21 U.S.C. § 360e(d)(2), but it does not

"require"—to use the language of § 360k(a)—any specific design, labeling, or manufacturing. *Lohr*'s observation that the FDA's labeling and manufacturing rules impose no "specific mandate on manufacturers or producers," 518 U.S. at 501, applies fully to the PMA process.

The courts that have found that § 360k(a) preempts damages claims have concluded that, given the degree of FDA scrutiny of PMA applications, PMA must have preemptive effect. *See, e.g., Horn v. Thoratec Corp.*, 376 F.3d 163, 169-70 (3d Cir. 2004); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 226-27 & n.4 (6th Cir. 2000). The Riegels agree that PMA may have a preemptive effect. The question is, what does PMA preempt? That is, what state requirement is the counterpart to a federal requirement mandating PMA for a particular device? The answer is, a state PMA requirement for that same device.

Accordingly, in a 1978 Federal Register notice, the FDA explained that state and local PMA requirements are preempted "on the date the device cannot lawfully be marketed without approval of an application" for federal PMA. 43 Fed. Reg. 18661, 18664 (1978). Consistent with this view, the FDA agreed that California could continue to require a state PMA before allowing any particular device to be marketed in California until the FDA established a "counterpart" requirement for that device—that is, until the date on which the FDA determined either that the device did not require PMA or that the device could not lawfully be marketed without a federal PMA. 45 Fed. Reg. 67321, 67323 (1980).

The principle that preemption under § 360k(a) turns on specific counterpart requirements is both consistent with the congressional purpose, *see supra* pp. 7, 16-17, and expressly stated in *Lohr*'s majority opinion. 518 U.S. at 500. Thus, the existence of one specific federal requirement applicable to a particular device does not preempt *all* state requirements applicable to that device. Rather, the federal requirement preempts only counterpart state requirements. *See id.* To use

the example from Justice Breyer's concurrence, a federal regulation mandating that hearing aids have two-inch wires would preempt a state requirement prescribing one-inch wires, *id.* at 505; but that federal regulation would not preempt state rules regarding packaging of hearing aids.

In short, the federal requirement that a device cannot be marketed without federal PMA preempts a state requirement that the device undergo state PMA but does not preempt state rules regarding other aspects of that device. Product liability claims for design defect or inadequate warning are not counterpart requirements to the requirement that a device receive PMA; such claims simply do not address the same topic (marketing approval). They are therefore not preempted by the federal PMA process.[7]

### 2. PMA Imposed No Device-Specific Design Requirements On The Device.

Although federal law required Medtronic to obtain PMA before marketing its catheter, the FDA, in granting PMA, did not impose specific requirements concerning the device's design. Like the design of the 510(k) pacemaker lead at issue in *Lohr*, the design of the catheter originated with the company. The FDA "did not 'require' [the device] to take any particular form for any particular reason." *Lohr*, 518 U.S. at 493 (no preemption of design-defect claim where FDA did not require Medtronic's pacemaker lead to adhere to any particular design).

Design specifications result from the manufacturer's decisions about how to design and whether to market the device. The FDA is not involved in device design, does not

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[7] That PMA does not preempt damages claims does not mean that it is irrelevant to the litigation of the claims. Under New York law, compliance with federal law may constitute evidence of due care in defense to negligence claims. *See, e.g., Feiner v. Calvin Klein, Ltd.*, 549 N.Y.S.2d 692, 693 (N.Y. App. Div. 1990); *accord* Restatement (Third) of Torts: Prods. Liab. § 4(b) (1988).

compare the relative risks or benefits of possible designs, and does not require a manufacturer to market any product. *Cf. American Airlines, Inc. v. Wolens*, 513 U.S. 219, 228-29 (1995) ("We do not read the [Airline Deregulation Act]'s preemption clause . . . to shelter airlines from suits alleging no violation of state-imposed obligations, but seeking recovery solely for the airline's alleged breach of its own, self-imposed undertakings."). And where a manufacturer has marketing approval for more than one model of its device, nothing in the PMA requires a manufacturer to market one approved design as opposed to another. *See, e.g., Blunt v. Medtronic, Inc.*, 2007 WL 2176136, ¶ 20 (Wis. Ct. App. July 31, 2007) (noting that FDA approval of safer defibrillator did not require Medtronic to stop marketing its inferior model).

PMA "represents only the FDA's judgment that a manufacturer has reasonably assured the FDA of the device's safety and effectiveness." *Webster v. Pacesetter, Inc.*, 171 F. Supp. 2d 1, 11 (D.D.C. 2001). The FDA does not impose through PMA particular design specifications comparable to the hypothetical FDA-required two-inch hearing-aid wire discussed in Justice Breyer's *Lohr* concurrence. 518 U.S. at 504. To be sure, the FDA by regulation *can* impose specific federal requirements with respect to design, labeling, or other characteristics of the device, 21 C.F.R. § 861.1(b)(3), in addition to the general criteria of "reasonable assurance of safety and effectiveness." Such requirements, however, "exist independently" of the PMA process. Br. of U.S. as Amicus Curiae at 15, *Smith Indus. Med. Sys. v. Kernats*, 522 U.S. 1044 (1998) (No. 96-1407) ("U.S. *Kernats* Br."). More importantly, with respect to the device at issue here, the FDA has issued no such requirement.

Here, the impossibility of conducting a "careful comparison" between a federal design requirement and a counterpart state requirement, as *Lohr* requires, 518 U.S. at 500, establishes that § 360k(a) does not preempt the Riegels' claims. If the FDA issued a standard requiring PTCA catheters to meet

certain specifications, *see* 21 C.F.R. § 861.1(b)(3), a design-defect claim that challenged the safety of the device could be analyzed in terms of whether design requirements implied by the claim (if any) were "different from or in addition to" those specifications. *See Lohr*, 518 U.S. at 504 (Breyer, J., concurring); *cf. Cipollone*, 505 U.S. at 524 (failure-to-warn claim preempted where federal law required particular warning); *Boyle v. United Techs. Corp.*, 487 U.S. 500, 512 (1988) (state tort claim against government contractor for design defects in equipment designed according to government specifications impliedly preempted).

For example, the FDA has issued specific performance parameters for certain lasers: "Device must emit a laser beam with the following parameters: wavelength = 1064 nanometers; spot size = 50 to 100 microns; pulse width = 3 to 30 nano-seconds . . . ." 21 C.F.R. § 886.4392. In a design-defect case involving this type of laser, one could look at the FDA-mandated performance parameters and evaluate whether state law sought to impose different or additional requirements—whether state law would require a different laser pulse width, for example, than that stated in the device-specific regulation. That scenario would still present the question whether the state-law duties upon which the plaintiff relied were specific enough to trigger preemption under § 360k(a) and whether the common-law design-defect claim reflected a state requirement related to the safety or effectiveness of a medical device. *See Oja v. Howmedica*, 111 F.3d 782, 789 (10th Cir. 1997) (holding damages claim not preempted by tampon-specific labeling requirement). At least, however, a court could compare the federal requirement to the state-law theory underlying the damages claim.

The absence of specific federal requirements for the design (or any other aspect) of Medtronic's device is underscored by the FDA's approval letter in this case. The letter imposes no specific requirements. *See* JA 16-17; *see also* JA 9-11 (approving original application for original model); JA 18-19,

26-27, 34-35 (letters approving later PMA supplements). And the "Conditions of Approval" is an FDA form document that applies to PMA products generally. *See* JA 12-15, 20-25, 28-33. Aside from listing in the November 1986 letter the types of patients for whom use of the product is indicated, none of the letters or Conditions of Approval says anything about catheters or Medtronic's product in particular. As the Eleventh Circuit, holding that PMA does not preempt state-law damages claims, observed:

> The "Conditions of Approval" document enclosed with the letter that noted the FDA's approval of the [device's] PMA application sets forth rules and regulations generally applicable to all devices approved through the PMA process. For example, the "Conditions of Approval" remind Medtronic of its obligation to provide post-approval reports, to refrain from changing the device without FDA approval, and to report adverse reactions and device defects. The document . . . is cast in the most generic of terms and mentions neither the [specific pacemaker lead] nor even pacemaker leads as a class of devices.

*Goodlin*, 167 F.3d at 1377.

Furthermore, as the Conditions of Approval explain, PMA does not lock the manufacturer into particular design specifications. Rather, FDA regulations allow a device manufacturer to obtain permission to alter the design of a PMA device by filing a PMA supplement. *See* 21 C.F.R. § 814.39. Medtronic itself filed two PMA supplements seeking to make design changes or to market new models of the PTCA catheter, and the FDA allowed both. JA 16, 26. Thus, the notion that PMA "required" a particular design is belied by applicable regulations and the facts of this case.

Moreover, although FDA regulations required Medtronic to obtain FDA authorization before changing the design of its catheter, the same was true with respect to the Medtronic

device at issue in *Lohr*. *Compare* 21 C.F.R. § 814.39 (manufacturer must submit PMA supplement before making change that affects safety or effectiveness of PMA device), *with id.* § 807.81(a)(3)(i) (manufacturer must submit new 510(k) application before making change that affects safety or effectiveness of 510(k) device). In *Lohr*, Medtronic relied on 21 C.F.R. § 807.81(a)(3)(i) to argue for preemption of the design claim, contending that the need to submit a new application before changing the design of its 510(k) device constituted a preemptive "requirement."[8] Yet the Court unanimously rejected the argument that the MDA preempted the design-defect claim. *Lohr*, 518 U.S. at 492-94 (majority); *id.* at 513 (O'Connor, J., concurring in part and dissenting in part).

### 3. PMA Imposed No Device-Specific Labeling Requirements On The Device.

For preemption purposes, the Riegels' inadequate warning claim is indistinguishable from the warning claim in *Lohr*. The claim is not preempted because, as was true in *Lohr*, Medtronic's device was subject only to the FDA's general labeling regulation. JA 10, 18, 27, 34 (approval letters). The FDA can issue a specific labeling regulation for a particular device. *See, e.g.*, 21 C.F.R. § 801.430(c)-(e) (specifying warning and other information for class II tampon labels); *id.* § 1020.30(j) (specifying warning for x-ray equipment). For most PMA and 510(k) devices (and for the catheter here), however, the FDA regulation governing the content of the label is 21 C.F.R. § 801.109—*the same regulation found too general to warrant preemption in Lohr*. *See* 518 U.S. at 497-501.

Like the 510(k) process, PMA does not lock the manufacturer into a particular label. Manufacturers can seek FDA

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[8] *See* Brief for Petitioner Medtronic, *Lohr*, 518 U.S. 470 (Nos. 95-754, 95-886), 1996 WL 88789, at *27-*28; Reply Brief for Petitioner Medtronic, *Lohr*, 518 U.S. 470 (Nos. 95-754, 95-886), 1996 WL 180309, at *13-*14.

permission to alter the labeling of a PMA device by filing a PMA supplement. *See* 21 C.F.R. § 814.39. Labeling changes that enhance the safety of the device by strengthening warnings or instructions or by deleting misleading information can even be made in advance of receiving FDA approval. *Id.* § 814.39(1)(d); *see Lohr*, 518 U.S. at 497 n.16 (suggesting this regulation's relevance to the preemption analysis); *see also infra* p. 42. With respect to the catheter at issue here, Medtronic filed two PMA supplements seeking to revise its label, and the FDA allowed both. JA 18, 34. Thus, PMA did not impose device-specific labeling requirements, and § 360k(a) does not preempt the inadequate warning claim here.

Finally, manufacturers can and do provide updated warning information through non-label means, such as "Dear Doctor" letters, which are not regulated by the FDA. The FDCA defines "labeling" as "all labels and other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers; or (2) accompanying such article." 21 U.S.C. § 321(m). Similarly, "'label' means a display of written, printed, or graphic matter upon the immediate container of any article." *Id.* § 321(k). Therefore, a post-PMA letter to physicians warning about the risk of over-inflation or clarifying that, although the label shows testing of the device up to 13 atmospheres, the device should not be inflated above 8 atmospheres, would not have constituted "labeling," and Medtronic was free to issue such a letter without approval from the FDA.

#### 4. FDA Regulations Support A Finding Of No Preemption.

*Lohr*'s construction of the statutory language is authoritative and cannot be altered by subsequent changes in the agency's reading of the statute: "Once we have determined a statute's clear meaning, we adhere to that determination under the doctrine of stare decisis, and we judge an agency's later interpretation of the statute against our prior determination of the statute's meaning." *Maislin Indus. v. Primary Steel, Inc.*,

497 U.S. 116, 131 (1990). Nonetheless, to the extent that the FDA's reading of § 360k(a) is entitled to weight in the judicial decisionmaking process, its analysis of the statute strongly supports the *Lohr* construction.

Although Congress did not delegate to the FDA the authority to define the term "requirements" in § 360k(a), the FDA has implemented its authority to grant exemptions from preemption under § 360k(b) through a set of regulations that narrowly construes § 360k(a)'s preemptive scope. The same regulations informed the Court's majority holding in *Lohr*, 518 U.S. at 496-97, 498-99 (majority opinion); *see also id.* at 505-06 (Breyer, J., concurring), and remain in effect, unaltered, today.

FDA regulations reinforce the conclusion that PMA does not impose requirements that preempt the Riegels' damages claims. As discussed above, *see supra* p. 7, the regulation addressing the scope of preemption, 21 C.F.R. § 808.1(d), provides that a state requirement is preempted only when the FDA has "established specific counterpart regulations" or when there are other "specific requirements applicable to the specific device" under the MDA that render a "divergent" state requirement "different from or in addition to" the "specific" FDA requirements. *See infra* 3a. In addition, the regulation addressing procedures for applying for an exemption assumes that a preempted "requirement" will be a "statute, rule, regulation, or ordinance of the State or political subdivision," and instructs the state to include in its exemption application "a reference to the date of enactment, promulgation, or issuance in final form. The application shall also include, where available, copies of any legislative history or background materials pertinent to enactment, promulgation, or issuance of the requirement, including hearing reports or studies concerning development or consideration of the requirement," and any judicial or administrative interpretations of such requirements. *Id.* § 808.20(c)(1) (*infra* 7a).

When it promulgated the regulations, the FDA set forth its interpretation of § 360k(a). Looking first to the words chosen by Congress—dictating that there be a pre-existing federal requirement "applicable to *the device*"—the agency found that device-specific federal rules must be in place before any preemption can occur. 43 Fed. Reg. 18662 (emphasis in original) (quoting § 360k(a)). The FDA further explained:

> Thus, from a plain reading of section [360k] of the act it is clear that the scope of preemption is limited to instances where there are specific FDA requirements applicable to a particular device or class of devices. . . . [A] prime example is the preemption of divergent State or local requirements relating to hearing aid labeling . . . , which occurred when the new FDA hearing aid regulations took effect. . . . [O]nly requirements relating to labeling and conditions for sale were preempted, not all State or local requirements regulating other facets of hearing-aid distribution.

*Id*; *see also* 42 Fed. Reg. 30383, 30384 (1977) (proposed rule) ("[A] preempting FDA requirement will become applicable to a device within the meaning of section [360k(a)] only after FDA takes a regulatory or administrative action involving the application of a particular requirement of the act to a particular device."). This insistence on specific federal requirements for the same subject matter regulated by the state—which the FDA refers to as the need for "specific counterpart" requirements—is found throughout the FDA's regulations. *See, e.g.*, 21 C.F.R. § 808.1(d)(3).

Although the United States argued in its amicus brief at the petition stage of this case that PMA broadly preempts state-law damages claims, the FDA's longstanding regulation—not the changing positions advocated in its amicus briefs—is entitled to weight. In the preemption context, this Court has given consideration to the views of the agencies to which Congress delegated regulatory authority where those views were

developed through notice-and-comment rulemaking. *See Geier v. American Honda Motor Co.*, 529 U.S. 861, 877-83 (2000) (in conflict preemption case, giving weight to agency's view of the purpose of a particular agency standard, where the view was stated contemporaneously with issuance of the standard and explained "consistently over time"); *Hillsborough County*, 471 U.S. at 714-15 (citing *Chevron U.S.A., Inc. v. Natural Res. Def. Council*, 467 U.S. 837, 842-45 (1984)).

In contrast, statements contained in government amicus briefs are not entitled to substantial weight. *See United States v. Mead Corp.*, 533 U.S. 218, 228 (2001); *Christensen v. Harris*, 529 U.S. 576, 587 (2000). This principle is particularly important here, where the government twice filed amicus briefs in this Court arguing against preemption, but then disavowed its own arguments and filed amicus briefs in a court of appeals and in this case taking the opposite position. *Compare* U.S. *Kernats* Br., *supra*, at 14-18, *and* Br. of U.S. as Amicus Curiae, *Lohr*, 518 U.S. 470 (No. 95-754), 1996 WL 118035, *with* Br. of U.S. as Amicus Curiae, *Riegel v. Medtronic, Inc.*, 451 F.3d 104 (2d Cir. 2006) (No. 06-179), *and* Br. of U.S. as Amicus Curiae, *Horn*, 376 F.3d 163 (No. 02-4597).

### B. The Riegels' Claims Also Are Not Preempted Because They Are Premised On State-Law Duties Of General Applicability.

Because the federal law's lack of device-specificity with respect to Medtronic's catheter is dispositive under *Lohr*, this Court need not reach the question whether the state-law claims at issue fall within the scope of § 360k(a). However, consideration of the claims independently shows that they would not impose state-law "requirements" that are "with respect to devices" under § 360k(a). Rather, even if damages claims can ever constitute requirements under § 360k(a), the principles of New York law on which the Riegels rely, like the Florida common-law duties on which the Lohrs relied, are

principles of "general applicability," *Lohr*, 518 U.S. at 500 (quoting 21 C.F.R. § 808.1(d)), outside the scope of § 360k(a).

**1.** Relying on the text of § 360k(a) and guided by the presumption against preemption, the *Lohr* majority held that state laws of general applicability, as opposed to laws specifically applicable to medical devices, are not preempted by the MDA. Accordingly, the Court held that the general duties to warn users of potential risks and to use due care in manufacturing are outside the prohibited category of requirements "with respect to" specific devices, within the meaning of § 360k(a).

The state-law side of the preemption analysis is unaffected by the factual difference between this case and *Lohr*—that is, that this case involves a PMA device and *Lohr* involved a 510(k) device. Because *Lohr*'s discussion of the state-law claims applies fully here, it is worth quoting extensively:

> [T]he general state common-law requirements in this case were not specifically developed "with respect to" medical devices. Accordingly, they are not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements. The legal duty that is the predicate for the Lohrs' negligent manufacturing claim is the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products. Similarly, the predicate for the failure to warn claim is the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use. These general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of a workforce.

*Lohr*, 518 U.S. at 501-02.

The agency's regulation takes this same approach, stating that § 360k(a) "does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (*e.g.*, requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices." 21 C.F.R. § 808.1(d)(1).

Thus, in *Lohr*, the state common-law claims "escape[d] preemption, not because the source of the duty [was] a judge-made common-law rule, but rather because their generality [left] them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices such as pacemakers." *Id.* at 502. As in *Lohr*, the general state common law at issue here was not developed "with respect to" medical devices. *See Horn*, 376 F.3d at 182 (Fuentes, J., dissenting). Rather, the claims are "predicated upon . . . general dut[ies] applicable to every manufacturer," such as the duty "to inform users and purchasers of potentially dangerous items of the risks involved in their use." *Lohr*, 518 U.S. at 501, *quoted in Oja*, 111 F.3d at 789 (device-specific federal labeling requirement did not preempt state-law claims based on general common-law duties that did not relate specifically to devices); *accord Niehoff v. Surgidev*, 950 S.W.2d 816, 822 (Ky. 1997) ("Kentucky's strict liability case law and statutes are laws of general applicability to all products and fall beyond the scope of federal preemption under § 360k.").[9]

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[9]*Accord Baird v. American Med. Optics*, 693 A.2d 904, 909-10 (N.J. Super. Ct. App. Div. 1997), *modified and remanded*, 713 A.2d 1019 (N.J. 1997); *Mears v. Marshall*, 944 P.2d 984, 993-95 (Or. Ct. App. 1997); *Wutzke v. Schwagler*, 940 P.2d 1386, 1391-92 (Wash. Ct. App. 1997); *Armstrong v. Optical Radiation Corp.*, 57 Cal. Rptr. 2d 763, 771-72 (Cal. Ct. App. 1996); *Kernats v. Smith Indus. Med. Sys.*, 669 N.E.2d 1300, 1309 (Ill. App. Ct. 1996); *Walker v. Johnson*

(continued...)

**2.** The United States, in its amicus brief at the petition stage in this case (at 13), tried to convert damages claims based on generally applicable state-law tort duties into device-specific requirements by asserting that a jury verdict would require Medtronic to change the design of its device. This Court has firmly rejected this argument:

> A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement. The proper inquiry calls for an examination of the elements of the common-law duty at issue, see *Cipollone*, 505 U.S. at 524; it does not call for speculation as to whether a jury verdict will prompt the manufacturer to take any particular action (a question, in any event, that will depend on a variety of cost/benefit calculations best left to the manufacturer's accountants).

*Bates*, 544 U.S. at 445. Thus, here, a jury verdict in favor of the Riegels would require Medtronic only to pay damages; it would not require Medtronic to take any action inconsistent with federal requirements. The possibility that manufacturers will have to pay damages—a possibility present since long before the MDA's enactment in 1976 and unquestioned by medical device manufacturers until the early 1990s—does not implicate § 360k(a). And the common-law duties at issue—the proper focus of inquiry under *Bates*—are not the types of specific requirements that § 360k(a) preempts.

Below, the court analogized a possible verdict against Medtronic to the hearing-aid wire example from Justice Breyer's concurrence in *Lohr*. Pet. App. 33a. That example is inapposite, and, in fact, Justice Breyer's concurrence weighs against preemption here and is consistent with the *Lohr*

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[9](...continued)
*& Johnson Vision Prods., Inc.*, 552 N.W.2d 679, 686 (Mich. Ct. App. 1996).

majority opinion (in which Justice Breyer joined). State damages claims are ordinarily premised on duties of general applicability, such as the duty to warn of risks or to use due care in the design of a product. Here, a verdict awarding damages would be based on Medtronic's dereliction of such duties. *See infra* pp. 41-42 (discussing New York law). That verdict would neither require Medtronic to change the device's design or label (even if Medtronic had not ceased to market this device), nor necessarily or even likely reflect a jury finding regarding a specific design or specific language that Medtronic failed to provide.

To be sure, a state's product liability law could require plaintiffs to prove tort claims with a higher degree of specificity. For instance, a jury instruction could allow the imposition of state-law liability on the ground that a medical device did not meet a particular state design or warning specification different from an FDA specification on the same subject. Or a jury instruction could state that, as a matter of law, the jury should find the manufacturer negligent if its device had one particular design feature rather than another--for instance, a 2-inch wire rather than a 1-inch wire. *See Horn*, 376 F.3d at 183-84 (Fuentes, J., dissenting). These examples reflect the view stated in Justice Breyer's concurrence that a *specific* federal design regulation would preempt a negligence claim based on the theory that the manufacturer should have used a different, *specific* design. *Lohr*, 518 U.S. at 504 (Breyer, J., concurring). Whether or not the state-law side of § 360k(a) would be satisfied in such instances, here, as in *Lohr*, no state requirements "with respect to medical devices" are at issue, and the generality of the state-law damages claims cannot rightly be said to create them. *See Bates*, 544 U.S. 431; *see also* U.S. *Kernats* Br. at 17 (making similar point).

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This Court need go no further than *Lohr* to hold that the Riegels' claims are not preempted. Both because the FDA has issued no device-specific regulations regarding the design or

labeling of PTCA catheters, and because the Riegels' state-law claims are based on laws of general applicability, § 360k(a) does not preempt the Riegels' claims.

## III. STATE REQUIREMENTS THAT PARALLEL FEDERAL REQUIREMENTS APPLICABLE TO PMA DEVICES ARE NOT PREEMPTED.

In *Lohr*, the Court held unanimously that § 360k(a) does not preempt state-law claims that parallel federal requirements. 518 U.S. at 495; *id.* at 513 (O'Connor, J., concurring in part and dissenting in part). As the Court explained, "Nothing in §360k denies [states] the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements." *Id.* at 495.

> Even if it may be necessary as a matter of [state] law to prove that those violations were the result of negligent conduct, or that they created an unreasonable hazard for users of the product, such additional elements of the state-law cause of action would make the state requirements narrower, not broader than the federal requirement.

*Id.*

The Court recently reiterated this holding in *Bates*. There, the Court recognized that an express preemption provision "similarly worded" to § 360k(a) did not preempt damages claims based on common-law duties equivalent to the duties imposed under the statute. 544 U.S. at 447. And the Court explained that a state-law duty equivalent to a federal duty "need not be phrased in identical language as its corresponding [federal] requirement." *Id.* at 454. Thus, here, the Riegels' claims are not preempted for the additional reason that they are based on duties that mirror federal design and labeling requirements.

Under New York law, a design-defect claim is premised on obligations equivalent to those imposed by federal law. New York law states these obligations very generally:

> [A] defectively designed product is one which, at the time it leaves the seller's hands, is in a condition not reasonably contemplated by the ultimate consumer and is unreasonably dangerous for its intended use; that is one whose utility does not outweigh the danger inherent in its introduction into the stream of commerce.

*Voss v. Black & Decker Mfg. Co.*, 450 N.E.2d 204, 207 (N.Y. 1983) (citations and internal quotation marks omitted).

Thus, like federal law, state common law prohibits marketing a device where the design is unreasonably dangerous or, to put it another way, requires that devices be designed to provide "reasonable assurance that the device is safe . . . [and] effective under the conditions of use prescribed, recommended, or suggested" in the label. 21 U.S.C. § 360e(d)(2)(A), (B) (standard for PMA); *see also id.* § 352(j) (product is misbranded if, among other things, it "is dangerous to health when used" as prescribed); *id.* § 331 (prohibiting misbranding).

PMA is a determination by the FDA that the device as designed and labeled presents a "reasonable assurance of safety and effectiveness," based on the information provided by the manufacturer in its application. 21 U.S.C. § 360c(a)(1)(C). However, PMA does not preclude a later determination that the device is not in fact safe and effective. Federal law recognizes that approved devices may sometimes prove *not* to be reasonably safe and effective, requiring a recall, alteration of the design or label, or other enforcement action. *Id.* §§ 360e(e) (withdrawal of approval), 360h(e) (recall authority). Accordingly, a state determination, through a damages verdict, that a device was not reasonably safe is consistent with the federal scheme.

Although the remedy under federal law would be for the FDA to withdraw approval of the device or to institute an enforcement action against the manufacturer, *id.* § 360e(e)(1), while the remedy under state law would be damages, the difference in remedies does not mean that state law imposes "different" or "addition[al]" requirements within the meaning of § 360k(a). As Justice O'Connor, concurring in *Lohr*'s unanimous holding, explained, "[s]ection 360k does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*." 518 U.S. at 513 (opinion concurring in part and dissenting in part).

The Riegels' inadequate warning claim similarly seeks to enforce duties parallel to the MDA's general labeling rules. New York common law requires a manufacturer to provide "adequate warnings regarding use of its product." 86 N.Y. Jur. 2d, Prods. Liab. § 51 (2007). "Liability may be premised upon the complete absence of warnings as to a particular hazard, or upon the inclusion of warnings [that] are insufficient." *El Sheikh v. Chem-Tainer Indus., Inc.*, 2006 WL 623464, at *4 (N.Y. Sup. Ct. Mar. 13, 2006); *see Cooley v. Carter-Wallace Inc.*, 478 N.Y.S.2d 375, 377 (N.Y. App. Div. 1984) ("warnings must clearly alert the user to avoid certain (unsafe) uses of the product which would appear to be normal and reasonable," and "to be adequate, the warnings must be commensurate with the risk involved in the ordinary use of the product") (citations omitted). A manufacturer may also incur liability for failing to warn of dangers that came to its attention after the product was manufactured or sold, through advancements in the state of the art or through reports of incidents involving dangers that warrant additional warnings. *See Cover v. Cohen*, 461 N.E.2d 864, 871 (N.Y. 1984).

Federal law prohibits the marketing of a misbranded product, 21 U.S.C. § 331(a), and specifies that a device is misbranded if its labeling "is false or misleading in any particular" or if the device "is dangerous to health when used in the . . . manner . . . prescribed, recommended or suggested in

labeling thereof," among other things. *Id.* §§ 352(a), (j). The generally applicable New York state-law duty to warn mirrors this general federal requirement.

In addition, Medtronic's catheter was subject to 21 C.F.R. § 801.109, *see* JA 10, 18, 27, 34, which requires that labels of both PMA and 510(k) devices include certain information, such as a statement that the device is restricted to "sale by or on the order of" a physician, the method of application or use, the date of issuance of the label, and, most significantly here, information about indications, route of administration, hazards, contraindications, precautions, and side effects. 21 C.F.R. § 801.109(b)-(d). The common-law duty and the federal duty in this regard are equivalent. Both call for instructions and warnings that adequately provide for safe use of the device.

Moreover, as explained above, FDA regulations recognize that approved labeling will often prove inadequate and, therefore, allow manufacturers of PMA devices to make certain labeling changes to enhance product safety *without* pre-approval from the FDA. 21 C.F.R. §§ 814.39(d)(1), (2); *see Lohr*, 518 U.S. at 497 n.16 (citing § 814.39(d) as further support for the holding that claims that parallel federal requirements are not preempted). In fact, because it is unlawful to sell a device that has received PMA but is, nonetheless, misbranded, 21 U.S.C. § 331(a), a manufacturer has a continuing obligation to amend labeling when it becomes aware that the approved labeling is false or misleading in any way. *See Bates*, 544 U.S. at 438 (making same point with regard to pesticides).

Here, although the device's label had been approved by the FDA, 21 C.F.R. § 814.39 allowed Medtronic to update the label as soon as it knew that the instructions or warnings were inadequate. To hold Medtronic liable under state law for failing to revise the label once it became aware (for example, through adverse event reports, *see* 2d Cir. App. A-637) that physicians were inflating the balloon catheter above 8

atmospheres and, therefore, that its label was not providing an adequate warning, would provide a remedy for the patient but would not impose any "different" or "additional" requirement on Medtronic. Accordingly, consistent with federal requirements, Medtronic may be held liable for failing to revise the labeling to clarify instructions or strengthen warnings.

Finally, the fact that, in civil cases, juries decide whether parallel state-law duties have been violated is no cause for concern. When a company is prosecuted for violating the FDCA, *e.g.*, *United States v. C.R. Bard, Inc.*, 848 F. Supp. 287, 288 (D. Mass. 1994) (felony prosecution involving PMA device), a jury may render the verdict at the criminal trial. Juries may also decide cases involving alleged violations of injunctions issued in connection with violations of 21 U.S.C. § 331, which includes misbranding. *Id.* § 332. In such a case, the jury makes its own determination about misbranding or adulteration, or whatever the alleged violation may be, and, of course, may disagree with the FDA. Thus, "lay juries are in no sense anathema to [the MDA's] scheme." *Bates*, 544 U.S. at 452 (making same point regarding enforcement of common-law duties that parallel federal standards under FIFRA).

## IV. MEDTRONIC'S POSITION WOULD IMPROPERLY FORECLOSE ALL REMEDIES FOR THE MANY PEOPLE INJURED BY PMA DEVICES.

The court of appeals believed that the scope of its decision was "actually quite limited" because most devices enter the market through the 510(k) process, not through PMA. *See* Pet. App. 13a, 36a. That statement was based on an inaccurate assumption that all devices—from bed pans, to bone cement, to heart valves—have an equal propensity for causing serious injury when defective and, therefore, are equally likely to be the subject of damages actions. PMA is required for life-sustaining devices and those that present the greatest risk of causing injury. 21 U.S.C. § 360c(a)(1)(C). Not surprisingly, those devices tend to cause a great many injuries and lawsuits. The

number of reported cases involving PMA devices, many of which are cited in the petition for certiorari and Medtronic's brief in opposition, speaks to the frequency of injuries and litigation attributable to PMA devices. Indeed, another one of Medtronic's PMA devices recently sparked so many cases as to warrant coordination in multidistrict litigation. *See In re Medtronic Implantable Defibrillators*, MDL No. 1726 (D. Minn.) (pending).

Examples of PMA devices that have caused serious injury are numerous:

• In August 2000, the FDA granted PMA to an implantable defibrillator manufactured by Guidant Corporation. In February 2002, Guidant began to receive reports that the device was short-circuiting. Shortly thereafter, in an effort to correct the problem, Guidant revised the design and manufacturing of the device. Nonetheless, it continued to sell the models made before the changes were implemented, and reports of device failures mounted. Guidant also started to receive reports of failures with another line of its implantable defibrillators. In March 2005, a patient died because of the failure of one of the devices. Yet Guidant apparently did not meet with the FDA to discuss the failures until May 2005. *See In re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig.*, MDL No. 05-1708, 2007 WL 1725289, at *1-*3 (D. Minn. June 12, 2007). Guidant issued a public notice about the problem in May 2005, reportedly after hearing that the "problems with the device . . . were going to be publicized in other forums." B. Meier, *Citing Flaws, Maker Recalls Heart Devices*, N.Y. Times, June 18, 2005, at A1. By June 2005, Guidant had determined that the problem was caused by degradation of the insulation material and had replaced that material. Only then did it recall the defective devices. *In re Guidant*, 2007 WL 1725289, at *2. Guidant sold 29,000 of the devices before it recalled them. Meier, *Citing Flaws*, *supra*. After the district court presiding over the multi-district litigation that arose from the injuries caused by the devices

denied Guidant's motion for summary judgment based on preemption, *In re Guidant*, 2007 WL 1725289, at *7-*11, the company agreed to settle the claims against it. *See In re Guidant*, 2007 WL 2071804 (D. Minn. July 16, 2007).

• A Thoratec heart pump was implanted in Daniel Horn in January 1998. The device used sutures to secure several parts that screwed into one another. On May 3, 1998, the pump broke when a factory-installed suture wore through, allowing a connection to loosen. The suture had run across the top of the device, which caused the suture to rub against the underside of Mr. Horn's sternum, which in turn caused the suture to break. As a result, a blood clot or air embolus traveled to Mr. Horn's brain, leaving him brain dead. The company later revised the product design to use self-locking screws, rather than thread, so that the screws would not loosen. The regulatory history of the device showed that the FDA had not required the suture to run along the top of the device and that the placement of the suture in relation to the sternum was not specifically addressed in the PMA application. *See Horn*, 376 F.3d 163 (finding all claims preempted).

• Medtronic's 4004M pacemaker lead received PMA from the FDA in 1989. Later, an FDA inspector discovered that the lead had a high probability of failure. The FDA subsequently instructed Medtronic to issue a Health Safety Alert letter informing physicians about the lead's flaw. In that letter, Medtronic told physicians to consider whether prophylactic replacement would be appropriate, especially for pacemaker-dependent patients. The letter advised physicians to replace the pacemaker lead if the risk of continued use outweighed the risk associated with implanting a new lead. *Goodlin*, 167 F.3d at 1368-69. Some patients died when the lead failed, and many patients were forced to undergo open-heart surgery to replace Medtronic's faulty lead. *See, e.g.*, *Cupek v. Medtronic, Inc.*, 405 F.3d 421 (6th Cir. 2005) (finding damages claims preempted); *Goodlin*, 167 F.3d 1367 (finding damages claims not preempted).

Many other PMA devices have caused injuries and deaths that led to significant litigation. *See, e.g., In re St. Jude Silzone Heart Valve Prods. Liab. Litig.*, MDL No. 01-1396 (D. Minn.) (pending multi-district litigation for Silzone-coated heart valve products); *In re Sulzer Hip Prosthesis and Knee Prosthesis Liab. Litig.*, 268 F. Supp. 2d 907, 912-13 (S.D. Ohio 2003) (more than 3880 patients required extra surgeries due to two defective PMA devices; more than 1300 lawsuits filed); *Bowling v. Pfizer, Inc.*, 143 F.R.D. 141 (S.D. Ohio 1992) (settlement of class action involving approximately 55,000 patients implanted with defective PMA heart valve).

Neither the MDA nor any other federal law provides any means for patients to obtain compensation for injuries caused by medical devices. Indeed, when Congress enacted the FDCA in 1938, it rejected a proposed federal right of action for damages because a common-law right of action already existed. *See Food, Drugs, and Cosmetics: Hearings Before a Subcomm. of the S. Comm. on Commerce on S. 1944*, 73d Cong. 10, 400, 403 (1933).

Where the federal regulatory scheme does not itself provide a damages remedy, the Court has ascribed preemptive intent to Congress only in the most compelling circumstances. *See English v. General Elec. Co.*, 496 U.S. 72, 87-90 (1990); *Silkwood*, 464 U.S. at 251; *see also Sprietsma*, 537 U.S. at 64. No such compelling circumstances are presented here, where, among other things, the legislative history is entirely silent on the topic, the MDA was intended to enhance consumer protection, FDA regulation of PMA devices is inadequate to prevent many serious injuries, and federal regulation and state-law damages remedies co-existed for more than a decade before even the device companies suggested that § 360k(a) preempts damages claims.

## CONCLUSION

The decision below should be reversed and the case remanded for a trial on the merits.

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# APPENDIX

## PRINCIPAL STATUTORY AND REGULATORY PROVISIONS INVOLVED

**21 U.S.C. § 360k provides:**

State and local requirements respecting devices

(a) General rule.—Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement--

(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and

(2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

(b) Exempt requirements.—Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a) of this section, under such conditions as may be prescribed in such regulation, a requirement of such State or political subdivision applicable to a device intended for human use if—

(1) the requirement is more stringent than a requirement under this chapter which would be applicable to the device if an exemption were not in effect under this subsection; or

(2) the requirement—

(A) is required by compelling local conditions, and

(B) compliance with the requirement would not cause the device to be in violation of any applicable requirement under this chapter.

**21 U.S.C. § 360h(d) provides:**

Effect on other liability.—Compliance with an order issued under this section shall not relieve any person from liability under Federal or State law. In awarding damages for economic loss in an action brought for the enforcement of any such

liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account.

**21 C.F.R. § 808.1 provides:**

(a) This part prescribes procedures for the submission, review, and approval of applications for exemption from Federal preemption of State and local requirements applicable to medical devices under section 521 of the act.

(b) Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

(c) Section 521(b) of the act contains a provision whereby the Commissioner of Food and Drugs may, upon application by a State or political subdivision, allow imposition of a requirement which is different from, or in addition to, any requirement applicable under the act to the device (and which is thereby preempted) by promulgating a regulation in accordance with this part exempting the State or local requirement from preemption. The granting of an exemption does not affect the applicability to the device of any requirements under the act. The Commissioner may promulgate an exemption regulation for the preempted requirement if he makes either of the following findings:

(1) That the requirement is more stringent than a requirement under the act applicable to the device; or

(2) That the requirement is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act.

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

(3) Section 521(a) does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or related professions or occupations that administer, dispense, or sell devices. However, regulations issued under section 520(e) or (g) of the act may impose restrictions on the sale, distribution,

or use of a device beyond those prescribed in State or local requirements. If there is a conflict between such restrictions and State or local requirements, the Federal regulations shall prevail.

(4) Section 521(a) does not preempt specifications in contracts entered into by States or localities for procurement of devices.

(5) Section 521(a) does not preempt criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health-care programs.

(6)(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good manufacturing practices beyond those prescribed in State or local requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.

(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

(7) Section 521(a) does not preempt State or local provisions respecting delegations of authority and related administrative matters relating to devices.

(8) Section 521(a) does not preempt a State or local requirement whose sole purpose is raising revenue or charging fees for services, registration, or regulatory programs.

(9) Section 521(a) does not preempt State or local requirements of the types that have been developed under the Atomic Energy act of 1954 (42 U.S.C. 2011 note), as amended, the Radiation Control for Health and Safety Act of 1968 (Pub.L. 90-602 (42 U.S.C. 263b et seq.)) and other Federal statutes, until such time as the Food and Drug Administration issues specific requirements under the Federal Food, Drug, and Cosmetic Act applicable to these types of devices.

(10) Part 820 of this chapter (21 CFR part 820) (CGMP requirements) does not preempt remedies created by States or Territories of the United States, the District of Columbia, or the Commonwealth of Puerto Rico.

(e) It is the responsibility of the Food and Drug Administration, subject to review by Federal courts, to determine whether a State or local requirement is equal to, or substantially identical to, requirements imposed by or under the act, or is different from, or in addition to, such requirements, in accordance with the procedures provided by this part. However, it is the responsibility of States and political subdivisions to determine initially whether to seek exemptions from preemption. Any State or political subdivision whose requirements relating to devices are preempted by section 521(a) may petition the Commissioner of Food and Drugs for exemption from preemption, in accordance with the procedures provided by this part.

(f) The Federal requirement with respect to a device applies whether or not a corresponding State or local requirement is preempted or exempted from preemption. As a result, if a State

or local requirement that the Food and Drug Administration has exempted from preemption is not as broad in its application as the Federal requirement, the Federal requirement applies to all circumstances not covered by the State or local requirement.

**21 C.F.R. § 808.20 provides:**

(a) Any State or political subdivision may apply to the Food and Drug Administration for an exemption from preemption for any requirement that it has enacted and that is preempted. An exemption may only be granted for a requirement that has been enacted, promulgated, or issued in final form by the authorized body or official of the State or political subdivision so as to have the force and effect of law. However, an application for exemption may be submitted before the effective date of the requirement.

(b) An application for exemption shall be in the form of a letter to the Commissioner of Food and Drugs and shall be signed by an individual who is authorized to request the exemption on behalf of the State or political subdivision. An original and two copies of the letter and any accompanying material, as well as any subsequent reports or correspondence concerning an application, shall be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. The outside wrapper of any application, report, or correspondence should indicate that it concerns an application for exemption from preemption of device requirements.

(c) For each requirement for which an exemption is sought, the application shall include the following information to the fullest extent possible, or an explanation of why such information has not been included:

(1) Identification and a current copy of any statute, rule, regulation, or ordinance of the State or political subdivision considered by the State or political subdivision to be a requirement which is preempted, with a reference to the date of

enactment, promulgation, or issuance in final form. The application shall also include, where available, copies of any legislative history or background materials pertinent to enactment, promulgation, or issuance of the requirement, including hearing reports or studies concerning development or consideration of the requirement. If the requirement has been subject to any judicial or administrative interpretations, the State or political subdivision shall furnish copies of such judicial or administrative interpretations.

(2) A comparison of the requirement of the State or political subdivision and any applicable Federal requirements to show similarities and differences.

(3) Information on the nature of the problem addressed by the requirement of the State or political subdivision.

(4) Identification of which (or both) of the following bases is relied upon for seeking an exemption from preemption:

(i) The requirement is more stringent than a requirement applicable to a device under the act. If the State or political subdivision relies upon this basis for exemption from preemption, the application shall include information, data, or material showing how and why the requirement of the State or political subdivision is more stringent than requirements under the act.

(ii) The requirement is required by compelling local conditions, and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act. If the State or political subdivision relies upon this basis for exemption from preemption, the application shall include information, data, or material showing why compliance with the requirement of the State or political subdivision would not cause a device to be in violation of any applicable requirement under the act and why the requirement is required by compelling local conditions. The application

shall also explain in detail the compelling local conditions that justify the requirement.

(5) The title of the chief administrative or legal officers of that State or local agency that has primary responsibility for administration of the requirement.

(6) When requested by the Food and Drug Administration, any records concerning administration of any requirement which is the subject of an exemption or an application for an exemption from preemption.

(7) Information on how the public health may be benefitted and how interstate commerce may be affected, if an exemption is granted.

(8) Any other pertinent information respecting the requirement voluntarily submitted by the applicant.

(d) If litigation regarding applicability of the requirement is pending, the State or political subdivision may so indicate in its application and request expedited action on such application.

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IN THE

# Supreme Court of the United States

DONNA S. RIEGEL, individually and as administrator of the estate of Charles R. Riegel,

*Petitioner,*

v.

MEDTRONIC, INC.,

*Respondent.*

**On Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit**

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## QUESTION PRESENTED

Whether the express preemption provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), preempts state-law claims seeking damages for injuries caused by medical devices that received premarket approval from the Food and Drug Administration.

## RULE 29.6 STATEMENT

The corporate disclosure statement included in the brief in opposition to the petition for a writ of certiorari remains accurate.

## TABLE OF CONTENTS


Page

QUESTION PRESENTED ..... i

RULE 29.6 STATEMENT ..... ii

TABLE OF AUTHORITIES ..... v

STATEMENT ..... 1

SUMMARY OF ARGUMENT ..... 11

ARGUMENT ..... 15

I. The PMA Process Imposes Device-Specific Federal "Requirements" On The Evergreen Balloon Catheter ..... 16

A. Unlike § 510(k) Review, The PMA Process Establishes Device-Specific Federal "Requirements" ..... 17

B. The Preemptive Effect Of PMA Approval Is Consistent With *Lohr* And The FDA's Regulatory Framework ..... 20

II. Petitioner's Common-Law Claims Seek To Impose State-Law "Requirements" "With Respect To" The Evergreen Balloon Catheter ..... 26

A. Common-Law Claims Constitute "Requirements" Under Section 360k(a) ..... 26

B. Petitioner's Common-Law Claims Would Impose "Requirements" That Are Specific To The Evergreen Balloon Catheter ..... 34

III. The State-Law "Requirements" That Petitioner Seeks To Impose Are "Different From" And "In Addition To" The Federal PMA "Requirements" ..... 40

IV. Preemption Of Petitioner's State-Law Claims Furthers The Objectives Of The MDA ..... 42

CONCLUSION ..... 50

## TABLE OF AUTHORITIES

**Page(s)**

### CASES

*Am. Airlines, Inc. v. Wolens*,
513 U.S. 219 (1995) ..... 24

*Bates v. Dow Agrosciences LLC*,
544 U.S. 431 (2005) ..... 13, 28, 41, 46

*BMW of N. Am., Inc. v. Gore*,
517 U.S. 559 (1996) ..... 37

*Buckman Co. v. Plaintiffs' Legal Comm.*,
531 U.S. 341 (2001) ..... 17, 18, 44

*Cipollone v. Liggett Group, Inc.*,
505 U.S. 504 (1992) ..... 13, 27, 31, 32, 38

*Crosby v. Nat'l Foreign Trade Council*,
530 U.S. 363 (2000) ..... 45

*Geier v. Am. Honda Motor Co.*,
529 U.S. 861 (2000) ..... 19, 44, 48

*Harrison v. PPG Indus., Inc.*,
446 U.S. 578 (1980) ..... 31

*Martin v. Medtronic, Inc.*,
254 F.3d 573 (5th Cir. 2001) ..... 18, 37

*MedImmune, Inc. v. Genentech, Inc.*,
127 S. Ct. 764 (2007) ..... 20

*Medtronic, Inc. v. Lohr*,
518 U.S. 470 (1996) ..... *passim*

*Pilot Life Ins. Co. v. Dedeaux*,
481 U.S. 41 (1987) ..... 32

*San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236 (1959) .....27, 38

*Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002).....22

*United States v. United Foods, Inc.*, 533 U.S. 405 (2001).....21, 40

*Watters v. Wachovia Bank, N.A.*, 127 S. Ct. 1559 (2007).....39

*Whitfield v. United States*, 543 U.S. 209 (2005).....31

**STATUTES**

Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539.....2

Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511.....4

5 U.S.C. § 504(a)(4) .....30

15 U.S.C. § 1334(b).....32

21 U.S.C. § 352 .....41

21 U.S.C. § 360(h).....19

21 U.S.C. § 360c.....3

21 U.S.C. § 360c(a)(1)(A)(i) .....3

21 U.S.C. § 360c(a)(1)(B).....3

21 U.S.C. § 360c(a)(1)(C).....3

21 U.S.C. § 360c(a)(2)(C).....17, 44, 47

21 U.S.C. § 360e(b)(1)(A).....4

21 U.S.C. § 360e(b)(1)(B).....4

21 U.S.C. § 360e(d)(1)(A)(i) .....6

21 U.S.C. § 360e(d)(2) ..... 5, 6
21 U.S.C. § 360e(d)(6)(A)(i) ..... 7, 17, 24
21 U.S.C. § 360h ..... 20
21 U.S.C. § 360h(a) ..... 21
21 U.S.C. § 360j(a) ..... 18
21 U.S.C. § 360k(a) ..... i, 2, 7, 9, 15, 34, 35
21 U.S.C. § 360k(a)(1) ..... 29, 30
21 U.S.C. § 360k(a)(2) ..... 29
21 U.S.C. § 360k(b) ..... 30
21 U.S.C. § 382(a)(2)(A) ..... 18
49 U.S.C. § 1305(a)(1)
(1998 ed. & Supp. V) ..... 24

**REGULATIONS**

21 C.F.R. § 801.109 ..... 20
21 C.F.R. § 808.1(b) ..... 28
21 C.F.R. § 808.1(d) ..... 12, 23, 30
21 C.F.R. § 808.1(d)(1) ..... 38
21 C.F.R. § 808.1(d)(6)(ii) ..... 35, 42
21 C.F.R. § 814.20(b)(4) ..... 6
21 C.F.R. § 814.44 ..... 6
21 C.F.R. § 814.44(e) ..... 23
21 C.F.R. § 814.84(b) ..... 19
42 Fed. Reg. 30,383 (June 14, 1977) ..... 39

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Gregory J. Scandaglia & Therese L. Tully, *Express Preemption and Premarket Approval Under the Medical Device Amendments*, 59 Food & Drug L.J. 245 (2004) ..... 5

## BRIEF FOR RESPONDENT

Respondent Medtronic, Inc., respectfully submits that the judgment of the court of appeals should be affirmed.

## STATEMENT

Petitioner is asserting state-law products liability claims challenging the design, manufacturing, and labeling of Medtronic's Evergreen Balloon Catheter, a life-saving medical device that the federal Food and Drug Administration ("FDA") found to be safe and effective after a thorough examination pursuant to its Premarket Approval ("PMA") process. Petitioner contends that a lay jury should be permitted to second-guess the FDA's expert determination regarding the Evergreen Balloon Catheter's safety and effectiveness because the PMA process at issue in this case is purportedly "similar to" the § 510(k) notification process (Pet. Br. 13), which this Court held not to have preemptive effect in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). Petitioner's characterization of the PMA process—and its preemptive force—is deeply flawed.

As this Court recognized in *Lohr*, the streamlined "§ 510(k) notification process is by no means comparable to the PMA process." 518 U.S. at 478-79. Whereas § 510(k) review entails no substantive evaluation of a device's safety and effectiveness (*id.* at 479), the PMA process requires manufacturers to "submit detailed information regarding the safety and efficacy of their devices," which the FDA spends hundreds of hours reviewing. *Id.* at 477. For devices that the FDA finds to be safe and effective, that "rigorous" process culminates in a set of device-specific design, manufacturing, and labeling requirements to

which the manufacturer must adhere in order to market its device. *Id.*

The Second Circuit held that petitioner's state-law claims "would, if successful, impose state requirements that differed from, or added to, the PMA-approved standards" established by the FDA, and are therefore expressly preempted by 21 U.S.C. § 360k(a). Pet. App. 32a. This conclusion is consistent with the plain language of Section 360k(a) and this Court's preemption analysis in *Lohr*. It also furthers the important legislative objectives that animate Section 360k(a)—which Congress enacted to prevent States from undermining the uniform federal regulatory framework that governs medical devices and from disturbing the FDA's expert regulatory judgments regarding the safety and effectiveness of such devices.

**A. Regulatory Background**

1. Until 1976, the FDA generally lacked authority to regulate medical devices. That year, Congress enacted the Medical Device Amendments ("MDA") to the federal Food, Drug, and Cosmetic Act ("FDCA"), which extended the FDA's regulatory authority to medical devices. Pub. L. No. 94-295, 90 Stat. 539.

In enacting the MDA, Congress sought to ensure that safe and effective medical devices would be readily available to treat patients in need of life-saving care. To that end, Congress crafted a regulatory framework that struck a careful balance between regulation and innovation. The MDA therefore "provide[s] for the safety and effectiveness of medical devices" (90 Stat. 539), while simultaneously "encourag[ing] the[ ] research and development" of "sophisticated, critically important" devices. S. Rep. No. 33, 94th Cong., 2d Sess. 2 (1975); *see also* H.R.

Rep. No. 853, 94th Cong., 2d Sess. 12 (the MDA "reflects the need to develop innovative new devices, consistent with the need to protect the subjects of device research").

The MDA establishes three classes of medical devices. 21 U.S.C. § 360c. Class I devices, such as tongue depressors, are devices for which the generally applicable design, manufacturing, and labeling standards established by the MDA "are sufficient to provide reasonable assurance of . . . safety and effectiveness." *Id.* § 360c(a)(1)(A)(i). Class II devices, such as hearing aids, are devices for which the "general controls" applicable to all devices are insufficient to provide a reasonable assurance of safety and effectiveness. *Id.* § 360c(a)(1)(B). Although such devices may be marketed without advance approval from the FDA, they must comply with additional federal performance regulations known as "special controls." *Id.* Class III devices, such as pacemakers, are those devices that either "present[ ] a potential unreasonable risk of illness or injury" or that are "represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," and for which neither general nor special controls would be sufficient to provide a reasonable assurance of safety and effectiveness. *Id.* § 360c(a)(1)(C).

The MDA provides that, before a Class III medical device can be marketed, it must be examined by the FDA through the rigorous PMA process and found to present a reasonable assurance of safety and effectiveness. 21 U.S.C. § 360c(a)(1)(C). As this Court recognized in *Lohr*, however, "[n]ot all, nor even most, Class III devices on the market today have received premarket approval because of two important exceptions to the PMA requirement." 518

U.S. at 477. First, the MDA permits medical devices that were commercially available before the statute's effective date to remain on the market until the FDA issues regulations requiring such devices to undergo the PMA process—a step that the FDA has taken for few pre-MDA devices. *Id.* at 478; *see also* 21 U.S.C. § 360e(b)(1)(A).

Second, the MDA provides that newly developed devices that are "substantially equivalent" to pre-MDA devices need not be approved under the PMA process in the absence of FDA regulations requiring PMA review. 21 U.S.C. § 360e(b)(1)(B). Those devices need only undergo a "limited form of review" known as the § 510(k) notification process, which requires the manufacturer to submit a report notifying the FDA of its intention to market a new device. *Lohr*, 518 U.S. at 478. The overwhelming majority of new Class III medical devices that reach the market do so through the § 510(k) notification process. Indeed, in fiscal year 2005, the FDA received 3130 § 510(k) notifications, but only 43 original PMA applications. *See* FDA Office of Device Evaluation, Annual Report Fiscal Year 2005, at 26, *at* www.fda.gov/cdrh/annual/fy2005/ode/report.pdf [hereinafter FDA, 2005 Annual Report].[1]

The FDA's review under the § 510(k) notification process is limited to whether the device is "substantially equivalent" to a pre-MDA device and does not extend to the device's safety or effectiveness. The

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[1] Congress has nevertheless expressed a strong preference for use of the PMA process, rather than the § 510(k) notification process, to introduce new medical devices. *See* Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 (requiring *all* Class III devices eventually to undergo PMA review).

FDA spends an average of only twenty hours reviewing a § 510(k) notification report (*Lohr*, 518 U.S. at 479), and approves nearly ninety percent of such submissions. FDA, 2005 Annual Report 36. In contrast, the FDA spends an average of 1200 hours reviewing a PMA submission (*Lohr*, 518 U.S. at 477), and approves less than sixty percent of such applications. FDA, 2005 Annual Report 36.

2. Class III devices that are not substantially equivalent to a pre-MDA device are not eligible for the § 510(k) notification process and must undergo PMA review. "PMA is the most stringent type of device marketing application required by FDA." FDA, Device Advice—Premarket Approval (PMA) 1, *at* http://www.fda.gov/cdrh/devadvice/pma/printer.html [hereinafter FDA, Premarket Approval]. During the PMA process, the FDA undertakes an extensive review of clinical studies and medical literature regarding the device, and a thorough examination of the device's design, manufacturing, and labeling to determine whether the device is safe and effective and therefore appropriate for marketing. 21 U.S.C. § 360e(d)(2). "PMA approval is based on a determination by FDA that the PMA [application] contains sufficient valid scientific evidence to assure that the device is safe and effective for its intended use(s)." FDA, Premarket Approval 1.

In contrast with a § 510(k) notification, which "'requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly'" (*Lohr*, 518 U.S. at 479), the PMA process is "extensive, time-consuming, and expensive," and consumes vast amounts of financial and human resources for both the device manufacturer and the FDA. Gregory J. Scandaglia & Therese L. Tully, *Express Preemption and Premarket Approval Under the*

*Medical Device Amendments*, 59 Food & Drug L.J. 245, 245 (2004). Submission of a PMA application to the FDA is generally preceded by years of painstaking research and development by the device manufacturer. The application that the manufacturer eventually submits to the FDA "involves many volumes of materials" that "include device description and intended use, nonclinical and clinical studies, case report forms, manufacturing methods, [and] labeling." FDA, Premarket Approval 18. The PMA application must include a "complete description" of the device; a "complete description" of the "methods used in . . . [its] manufacture, processing, packing, [and] storage"; the results of nonclinical studies with the device, including microbiological, toxicological, stress, wear, and shelf life; the results of clinical investigations involving human subjects, including safety and effectiveness data, adverse reactions and complications, and device failures and replacements; a bibliography of all published reports regarding the device's safety and effectiveness; and copies of all proposed labeling for the device. 21 C.F.R. § 814.20(b)(4); *see also* FDA, Premarket Approval 21-24. As part of the PMA process, the FDA may refer the application to an advisory panel of outside experts for consideration and a recommended disposition; all applications for first-of-a-kind devices are submitted to such a panel. 21 C.F.R. § 814.44; *see also* FDA, Premarket Approval 7.

The FDA issues an approval order for a device if it finds that there is a reasonable assurance of safety and effectiveness when the device is designed, manufactured, and labeled in accordance with the specifications of its PMA application. 21 U.S.C. § 360e(d)(1)(A)(i); *id.* § 360e(d)(2). The approval order authorizes the manufacturer to market the de-

vice in accordance with those design, manufacturing, and labeling specifications. J.A. 16. The order is accompanied by a set of Conditions of Approval that require the manufacturer to submit a PMA supplement for any changes to the device that affect its safety and effectiveness, and that prohibit the manufacturer from marketing the modified device before obtaining FDA approval of the supplemental application. 21 U.S.C. § 360e(d)(6)(A)(i).

In developing this comprehensive regulatory framework for medical devices, Congress recognized that state-law requirements could undermine the public health by imposing overlapping and potentially irreconcilable obligations on device manufacturers and by displacing the FDA's expert regulatory judgments regarding a device's safety and effectiveness. Congress therefore included Section 360k(a) in the MDA as a "general prohibition on non-Federal regulation" of medical devices. H.R. Rep. No. 853, 94th Cong., 2d Sess. 45 (1976). That provision expressly preempts state-law requirements applicable to medical devices that are "different from, or in addition to," requirements established by the FDA. 21 U.S.C. § 360k(a).

In *Lohr*, this Court held that Section 360k(a) did not expressly preempt state-law products liability claims regarding a pacemaker that had entered the market through the § 510(k) notification process. In so holding, the Court took great pains to distinguish the "limited form of review" of the § 510(k) notification process from the "rigorous" scrutiny of the PMA process. *Lohr*, 518 U.S. at 478.

**B. Proceedings Below**

1. Medtronic's Evergreen Balloon Catheter is a Class III medical device that underwent the FDA's

PMA process. Medtronic developed the device for use by licensed physicians to open the clogged arteries of patients suffering from coronary disease. Pet. App. 3a. During an angioplasty procedure, the catheter is inserted into the artery, inflated with saline solution, and then deflated once the procedure is complete. *Id.*

After reviewing the device specifications and clinical and nonclinical studies that Medtronic submitted as part of its PMA application, the FDA found that the Evergreen Balloon Catheter is safe and effective for its intended use when it is designed, manufactured, and labeled in accordance with the specifications of its PMA application. J.A. 16. The Conditions of Approval attached to the PMA approval letter required that "[b]efore making any change affecting the safety or effectiveness of the device," Medtronic "submit a PMA supplement for review and approval by FDA." *Id.* at 20. "Failure to comply with the conditions of approval," the FDA cautioned, "invalidates this approval order" and constitutes a "violation of the Federal Food, Drug, and Cosmetic Act." *Id.* at 16.

After receiving PMA approval, Medtronic designed, manufactured, and labeled the Evergreen Balloon Catheter in accordance with the specifications set forth in its PMA application, and did not modify the device until the FDA had approved the requisite PMA supplement. J.A. 18, 26.

The Evergreen Balloon Catheter was used during an angioplasty procedure to treat Charles Riegel's "diffusely diseased" and "heavily calcified" right coronary artery. Pet. App. 4a. The treating physician elected to use the Evergreen Balloon Catheter after his attempts to use other devices, including

other catheters, had proved unsuccessful. The physician selected the Evergreen Balloon Catheter even though the labeling of the device clearly states that it should not be used in patients, such as Mr. Riegel, who have "diffuse or calcified stenoses." *Id.* After inserting the Evergreen Balloon Catheter into Mr. Riegel's artery, the physician inflated the device several times, up to a pressure of ten atmospheres—again directly contravening the device's label, which warns that it should not be inflated beyond eight atmospheres. *Id.* On the final inflation, the device burst, seriously injuring Mr. Riegel. *Id.*

2. Petitioner filed this diversity action against Medtronic in the United States District Court for the Northern District of New York, alleging state-law claims for negligent design, testing, inspection, manufacture, distribution, labeling, marketing, and sale of the Evergreen Balloon Catheter; strict liability; and breach of express and implied warranty. Pet. App. 4a-5a.

The district court granted Medtronic summary judgment on petitioner's negligence, strict liability, and implied warranty claims on the ground that those claims were expressly preempted by 21 U.S.C. § 360k(a).[2]

3. The Second Circuit affirmed. Applying the plain language of Section 360k(a), as construed by this Court in *Lohr*, the court held that petitioner's products liability claims, if successful, would impose

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[2] The district court later granted summary judgment to Medtronic on petitioner's remaining negligent manufacturing and express warranty claims on grounds other than preemption, and those claims are no longer at issue in this case. Pet. App. 90a.

specific state-law "requirements" that would be "different from, or in addition to," the device-specific requirements that the FDA established for the Evergreen Balloon Catheter through its PMA approval order.

The Second Circuit surveyed the features of the "lengthy and rigorous" PMA process (Pet. App. 8a), and concluded that the Evergreen Balloon Catheter and other PMA-approved devices "are subject to federal device-specific requirements." *Id.* at 25a. The court reasoned that, unlike the § 510(k) process, "PMA approval explicitly signifies the FDA's substantive approval of the device's reasonable safety and effectiveness." *Id.* at 27a. Because "the manufacturer cannot make any changes that might affect the safety and effectiveness of the device without further FDA approval," the court continued, a PMA-approved device "is clearly subject to the federal, device-specific requirement of adhering to the standards contained in its individual, federally approved PMA." *Id.* at 26a.

Turning to the state side of the preemption framework, the Second Circuit emphasized that, "[i]n *Lohr*, . . . five justices . . . endorsed the view that § 360k(a)'s reference to state 'requirements' encompassed state common law tort lawsuits." Pet. App. 30a. The court concluded that, "if successful," petitioner's state-law claims would therefore "impose state requirements" regarding the design, manufacturing, and labeling of the Evergreen Balloon Catheter that "differed from, or added to, the PMA-approved standards" for the device. *Id.* at 32a. "[S]uch a situation," the court explained, "would be quite analogous to the hypothetical situation posed by Justice Breyer in his *Lohr* concurrence, in which, notwithstanding a federal requirement for a 2-inch

hearing wire in a particular hearing aid, a plaintiff brought a tort claim relating to the same hearing aid that premised liability on the manufacturer's failure to use a wire that was 1-inch or less." *Id.* at 33a.

The Second Circuit emphasized that its "finding of preemption is consistent" with both Congress's objective in enacting the MDA "to ensure that innovations in medical device technology are not stifled by unnecessary restrictions" (Pet. App. 34a (internal quotation marks omitted)) and with the "FDA's recent determination that preemption is warranted with respect to this universe of cases." *Id.* at 37a. The court also explained that the "scope of [its] decision is . . . quite limited" because the "vast majority of Class III medical devices enter the market pursuant to the § 510(k) process" and this Court "has already held in *Lohr* that tort claims as to § 510(k)-cleared devices are not preempted." *Id.* at 36a.

## SUMMARY OF ARGUMENT

Petitioner's claims seek to impose state "requirements" "with respect to" the design, manufacturing, and labeling of the Evergreen Balloon Catheter that are "different from" and in "addition to" the device-specific federal requirements established by the Evergreen Balloon Catheter's PMA approval order. These claims are therefore expressly preempted by Section 360k(a).

I. The Second Circuit correctly determined that the PMA process imposes device-specific federal requirements on medical devices.

A. Unlike the streamlined § 510(k) notification process, the rigorous PMA procedure involves a substantive evaluation of a device's safety and effectiveness. The FDA grants PMA approval only if it determines that a device is safe and effective when de-

signed, manufactured, and labeled in accordance with the specifications of its PMA application. Because a manufacturer is prohibited from modifying a PMA-approved device in a manner that could impact its safety or effectiveness, the design, manufacturing, and labeling specifications set forth in the PMA application and approved by the FDA constitute a set of federal device-specific requirements with which a PMA-approved device, such as the Evergreen Balloon Catheter, must comply.

B. This Court's holding in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), and the FDA's regulatory framework support the conclusion that PMA approval has preemptive effect. In *Lohr*, the only manufacturing and labeling requirements applicable to the § 510(k)-cleared device were the generic FDA manufacturing and labeling regulations that are applicable to all medical devices. The Evergreen Balloon Catheter, in contrast, is subject not only to those generic requirements but also to the device-specific manufacturing and labeling requirements set forth in the FDA-approved PMA application. Similarly, the FDA regulations on which petitioner relies do not suggest that only device-specific FDA regulations can have preemptive effect, but instead demonstrate that both "specific counterpart regulations" *and* "specific requirements"—such as the device-specific requirements established by PMA approval—can give rise to preemption. 21 C.F.R. § 808.1(d).

II. The Second Circuit also correctly held that petitioner's claims seek to impose specific state-law "requirements" on the Evergreen Balloon Catheter.

A. A majority of this Court held in *Lohr* that state common-law claims constitute "requirements" within the meaning of Section 360k(a). This conclu-

sion is consistent with this Court's unbroken line of decisions holding that the term "requirement" encompasses common-law claims when used in a preemption provision. *See Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (plurality op.); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 443 (2005). Petitioner's argument that Section 360k(a) does not preempt *any* state common-law claims is therefore squarely foreclosed by precedent.

Moreover, nothing in the language or legislative history of the MDA supports a contrary reading of the term "requirement." While the context in which the term is used in other provisions of the MDA may arguably limit its scope to positive enactments, Section 360k(a) gives the term its broadest possible meaning by referring to "*any* requirement" established by a State. The MDA's legislative history cannot displace the unambiguous meaning of this phrase. In any event, contrary to petitioner's assertion, it is far from "unprecedented" for Congress to preempt a small class of state-law claims without providing an alternate federal remedy, where doing so is essential to achieving an important federal objective, such as promoting the public health through the establishment of a comprehensive federal regulatory framework for medical devices.

B. Petitioner's claims would impose state "requirements" that are specific to the Evergreen Balloon Catheter. As Justice Breyer recognized in his *Lohr* concurrence, there is no difference for preemption purposes between a requirement imposed on a medical device by a state regulation and one imposed by state common law.

If this case reaches trial, a jury will be required to decide whether, when applied to the Evergreen

Balloon Catheter, New York common law imposes design, manufacturing, and labeling requirements with which the device failed to comply. A verdict in petitioner's favor would therefore have the same practical effect as a New York regulation requiring Medtronic to design, manufacture, and label the Evergreen Balloon Catheter in a manner different than that approved by the FDA. These substantive, device-specific requirements—whether imposed by common law or regulation—are preempted by Section 360k(a).

III. Petitioner never argued below that her state-law claims escape the preemptive reach of Section 360k(a) because they are "parallel" to the federal requirements imposed by the PMA approval order. This Court therefore need not reach that issue. In any event, the argument is unavailing because petitioner's state-law claims rest on the premise that the Evergreen Balloon Catheter was defective under state law *despite* being designed, manufactured, and labeled in conformity with its PMA specifications. The state-law requirements that petitioner is seeking to impose are therefore directly at odds with—rather than parallel to—the Evergreen Balloon Catheter's PMA requirements.

IV. Finally, preemption of petitioner's state-law claims furthers the MDA's regulatory objectives.

A. Congress enacted the MDA to promote the public health by ensuring the widespread availability of safe and effective medical devices. Congress intended for the MDA's regulatory framework to draw a careful balance between the goals of safety and technological innovation. Preemption of state-law claims challenging the design, manufacturing, and labeling of PMA-approved devices is essential to at-

taining Congress's public-health objectives because, in the absence of preemption, medical device manufacturers would be subject to overlapping—and potentially irreconcilable—state and federal regulatory requirements. The existence of such conflicting regulatory standards would significantly complicate the task of bringing new medical devices to market. Moreover, without preemption, lay juries would be empowered to second-guess the FDA's expert regulatory judgments regarding the safety and effectiveness of PMA-approved devices. For this reason, the FDA itself supports preemption in this case.

B. The class of plaintiffs left without a common-law remedy by the Second Circuit's holding is exceedingly small. The vast majority of medical devices reach the market through the § 510(k) notification process, which does not preempt state-law claims. In addition, even PMA-approved devices are subject to breach-of-warranty and negligent manufacturing claims because those claims are not "different from" or "in addition to" the federal requirements to which a PMA-approved device must adhere.

The judgment below should be affirmed.

## ARGUMENT

Federal law expressly prohibits States from "establish[ing] or continu[ing] in effect with respect to a device intended for human use any requirement which is different from, or in addition to, any requirement applicable under [the FDCA] to the device, and which relates to the safety or effectiveness of the device." 21 U.S.C. § 360k(a). As the Second Circuit held, each of the statutory prerequisites to preemption is satisfied in this case.

The Evergreen Balloon Catheter is subject to a set of federal, device-specific design, manufacturing,

and labeling "requirements" embodied in its FDA-approved PMA application. Petitioner's claims allege that New York law also establishes specific substantive standards for the Evergreen Balloon Catheter's design, manufacturing, and labeling, and that the device failed to comply with those state-law standards. These claims therefore constitute state-law "requirement[s]" "with respect to" the device that are "different from" and "in addition to" the device-specific design, manufacturing, and labeling "requirements applicable under [the FDCA]." Finally, these state-law requirements relate to the "safety or effectiveness" of the Evergreen Balloon Catheter because they rest on the allegation that—when designed, manufactured, and labeled in accordance with its PMA specifications—the device was unsafe and did not effectively perform its intended function when used to treat Mr. Riegel.

Because petitioner is directly challenging the FDA's expert judgment that the Evergreen Balloon Catheter is safe and effective, her claims are foreclosed by Section 360k(a).

## I. THE PMA PROCESS IMPOSES DEVICE-SPECIFIC FEDERAL "REQUIREMENTS" ON THE EVERGREEN BALLOON CATHETER.

The Second Circuit held that a medical device that has obtained PMA approval is "subject to the federal, device-specific requirement of adhering to the standards contained in its individual, federally approved PMA," and that these requirements therefore have preemptive force under Section 360k(a). Pet. App. 26a. This conclusion is consistent with this Court's description of the "rigorous," device-specific FDA inquiry that every PMA device must undergo—an inquiry that this Court repeatedly distinguished

from the "limited" and "by no means comparable" § 510(k) notification process. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996).

### A. Unlike § 510(k) Review, The PMA Process Establishes Device-Specific Federal "Requirements."

The PMA process involves an "exhaustive" and "time-consuming" review of a medical device's design, manufacturing, and labeling. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344, 349 (2001). The FDA spends hundreds of hours during the PMA process reviewing clinical and nonclinical studies to determine whether a particular device would be safe and effective when designed, manufactured, and labeled in conformity with the specifications set forth in the voluminous PMA application. *See Lohr*, 518 U.S. at 477. On the basis of this information, the FDA "weigh[s] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C).

PMA approval signals that the FDA has found the device to be safe and effective when designed, manufactured, and labeled in conformity with the specifications of the PMA application. FDA, Premarket Approval 1. Accordingly, upon receiving approval, the manufacturer may market the device *only* as specified in the PMA application approved by the FDA. Any change to the device's design, manufacturing, or labeling that affects its safety or effectiveness must be approved by the FDA before the modified device may be marketed. 21 U.S.C. § 360e(d)(6)(A)(i); J.A. 21. The FDA's approval of a PMA application therefore establishes a set of device-specific design, manufacturing, and labeling re-

quirements to which the manufacturer must adhere. *Cf.* 21 U.S.C. § 360j(a) (referring to "requirement[s] imposed on [a] device under section . . . 360e," which governs the PMA process); *id.* § 382(a)(2)(A) (same).

These device-specific requirements embody the substantive judgment of the FDA regarding a device's safety and effectiveness, and distinguish the PMA process from the streamlined § 510(k) notification process considered in *Lohr*. In contrast with the PMA process—which is "specifically focused on safety and requires a significant weighing of considerations specific to the device before approval is granted" (*Martin v. Medtronic, Inc.*, 254 F.3d 573, 584 (5th Cir. 2001))—"the § 510(k) process lacks the PMA review's rigor" and "requires only a showing of substantial equivalence to a predicate device." *Buckman*, 531 U.S. at 348. The pacemaker lead at issue in *Lohr* thus had never been reviewed by the FDA for safety and effectiveness because it reached the market through the § 510(k) notification process. In authorizing the manufacturer to market the product, the FDA had merely concluded that the pacemaker lead was "substantially similar" to a device that had been marketed before the enactment of the MDA. Indeed, when communicating to the manufacturer that the device had cleared the § 510(k) notification process, the FDA "emphasized . . . that this determination should not be construed as an endorsement of the pacemaker lead's safety." *Lohr*, 518 U.S. at 480. Although the pacemaker lead was subject to manufacturing and labeling requirements applicable to all medical devices, this Court explained that they did not have preemptive effect because they "reflect[ed] important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation that

the [MDA] statute or regulations were designed to protect from potentially contradictory state requirements." *Id.* at 501.

PMA-approved devices, in contrast, are subject to a set of requirements that embody precisely "the sort of concerns regarding a specific device" that Congress intended to insulate from different or additional state-law requirements. FDA approval of a PMA application reflects the agency's device-specific determination that the product is safe and effective and therefore appropriate for marketing in conformity with the design, manufacturing, and labeling specifications approved by the FDA. The MDA shields these expert agency determinations from conflicting state-law evaluations of safety and effectiveness. *See Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 871 (2000) (preemption of state-law safety standards is necessary "to avoid the conflict, uncertainty, cost, and occasional risk to safety itself that too many different safety-standard cooks might otherwise create").[3]

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[3] Contrary to the contention of *amicus curiae* AARP that the PMA process is merely a "one-time licensing scheme" (Br. of AARP et al. 14), the FDA's stringent oversight of the safety and effectiveness of PMA-approved devices does not end when an approval order is issued. A manufacturer of a PMA-approved device is required to submit an annual report to the FDA summarizing additional clinical and nonclinical studies regarding the device (21 C.F.R. § 814.84(b)), and to inform the FDA within ten days of learning that a device has caused an adverse reaction in a patient. J.A. 23. The FDA also undertakes periodic inspections of the facilities at which PMA-approved devices are manufactured in order to ensure that they are being produced in compliance with the manufacturing methods specified in the PMA application and approved by the FDA. 21 U.S.C. § 360(h); FDA, Premarket Approval 34. Where the FDA determines that a PMA-approved device presents an unreasonable risk of sub-

### B. The Preemptive Effect Of PMA Approval Is Consistent With *Lohr* And The FDA's Regulatory Framework.

Petitioner advances five contrary arguments in an effort to obscure the existence of these preemptive, device-specific federal requirements. Each of petitioner's arguments is unavailing.

First, petitioner is wrong to contend that Medtronic is relying upon the same federal requirements that were considered in *Lohr* as the basis for preemption. Pet. Br. 30. Petitioner argues, for example, that the federal labeling requirements at issue in this case are no different than those in *Lohr*. *Id.* But while the pacemaker lead in *Lohr* was only subject to the FDA's general labeling requirements (*see, e.g.*, 21 C.F.R. § 801.109)—which this Court found to be insufficiently device-specific to trigger preemption (518 U.S. at 501)—the FDA substantively reviewed the proposed labeling for the Evergreen Balloon Catheter set forth in its PMA application, approved that labeling as adequate to ensure safety and effec-

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[Footnote continued from previous page]

stantial harm to the public, it can order the manufacturer to repair, replace, or cease distribution of the device, or can order a recall of the device. 21 U.S.C. § 360h. Petitioner nevertheless contends that the FDA's postmarket surveillance is somehow deficient because the FDA is not frequently required to issue a recall order to secure the removal of a dangerous device from the market but has generally been able to rely on manufacturers' voluntary compliance with its recall requests. *See* Pet. Br. 6 & n.2. Conduct taken under the threat of government action, however, is just as much the product of government regulation as conduct that the government has explicitly directed a person to undertake. *See, e.g., MedImmune, Inc. v. Genentech, Inc.*, 127 S. Ct. 764, 772-73 (2007).

tiveness, and precluded Medtronic from making changes without further FDA approval. The Evergreen Balloon Catheter thus must adhere to these device-specific labeling requirements, not simply to the general labeling requirements that this Court considered in *Lohr*. *See Lohr*, 518 U.S. at 501 (distinguishing the "generality of those requirements" applicable to a § 510(k)-cleared device from "a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers").[4]

Second, petitioner argues that—notwithstanding the device-specific design, manufacturing, and labeling requirements established by PMA approval of the Evergreen Balloon Catheter—the MDA's preemption

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[4] Petitioner attempts to evade the MDA's preemptive reach by arguing that Medtronic could have issued a "Dear Doctor" letter informing physicians of the purported defects in the Evergreen Balloon Catheter. Pet. Br. 31. Petitioner did not raise that argument below, and this Court therefore need not reach it. *See United States v. United Foods, Inc.*, 533 U.S. 405, 416-17 (2001). In any event, petitioner's argument is without merit because FDA regulations define the scope of Medtronic's obligation to inform doctors about potential device defects in PMA-approved devices. *See* 21 U.S.C. § 360h(a). The mere fact that federal law *allows* a manufacturer to send a "Dear Doctor" letter does not mean that federal law *requires* a manufacturer to do so. Were state-law tort liability premised on Medtronic's failure to do something that is permitted but not required under federal law, state law would clearly be imposing a preempted requirement "different from, or in addition to," the federal requirements applicable to the Evergreen Balloon Catheter.

provision should be confined to federal requirements established by an FDA-promulgated regulation. Pet. Br. 27-28. But this artificially narrow reading of Section 360k(a) collapses under scrutiny.

Petitioner effectively concedes that the FDA could preempt different or additional state-law requirements regarding the design, manufacturing, or labeling of the Evergreen Balloon Catheter by promulgating a set of regulations that embodied the FDA's expert regulatory judgment regarding those features of the device. *See* Pet. Br. 27 ("If the FDA issued a standard requiring PTCA catheters to meet certain specifications, a design-defect claim that challenged the safety of the device could be analyzed in terms of whether design requirements implied by the claim (if any) were different from or in addition to those specifications.") (internal quotation marks and citation omitted). Petitioner nevertheless insists that the FDA's approval of Medtronic's PMA application—which signals that, in the FDA's expert regulatory judgment, the device is safe and effective when designed, manufactured, and labeled in conformity with the PMA application's specifications—does not have preemptive effect.

Both petitioner's hypothetical set of regulations and the PMA approval order, however, embody the same expert regulatory determination regarding the Evergreen Balloon Catheter's safety and effectiveness; there is simply no principled basis—and certainly no basis in the language of Section 360k(a)—for affording that device-specific regulatory judgment preemptive effect only when embodied in a regulation. *Cf. Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) (recognizing that even an agency's decision not to engage in regulation can have preemptive effect). Indeed, the FDA regulation on which peti-

tioner relies to substantiate her insistence on the promulgation of an agency regulation as a prerequisite to preemption provides that "[s]tate or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are *other specific requirements* applicable to a particular device under the" MDA. 21 C.F.R. § 808.1(d) (emphasis added). The phrase "other specific requirements" must refer to something other than the "specific counterpart regulations" also mentioned in Section 808.1(d). In this case, those "other specific requirements applicable to a particular device" are the device-specific design, manufacturing, and labeling specifications that the FDA established—and from which the Evergreen Balloon Catheter may not deviate—when it approved Medtronic's PMA application.

Third, petitioner asserts that the FDA does not itself develop the design, manufacturing, or labeling for a PMA-approved device and that this precludes the PMA process from establishing device-specific requirements. Pet. Br. 24. Petitioner is wrong to suggest that the FDA never develops a device's design, manufacturing, or labeling specifications. The FDA can direct a manufacturer to alter its proposed specifications for a device as a condition of receiving PMA approval, and there is often substantial back-and-forth between the FDA and the manufacturer during the PMA process. 21 C.F.R. § 814.44(e). In any event, it is completely irrelevant to the preemption inquiry whether the FDA avails itself of its authority to direct modification of a product's design, manufacturing, and labeling or whether it concludes that the device is safe and effective when marketed in accordance with the specifications developed by the manufacturer. Petitioner cites nothing in the

MDA to support such a distinction. Whether the design, manufacturing, and labeling specifications approved by the FDA were proposed by the FDA itself or by the manufacturer, the PMA approval order establishes a set of device-specific requirements from which the manufacturer may not deviate and that preempt counterpart state requirements. Indeed, it would be ironic, to say the least, if the MDA afforded less preemption protection to the manufacturer of a device that the FDA found to be safe and effective based on the specifications in its initial PMA application than to a manufacturer that was required by the FDA to make design, manufacturing, or labeling changes in order to obtain PMA approval.[5]

Fourth, the generality of the approval letter notifying Medtronic that its PMA application for the Evergreen Balloon Catheter had been approved is also irrelevant to the preemption inquiry. Pet. Br. 28-29. It is not the approval letter or the Conditions of Ap-

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[5] Petitioner is wrong to rely upon *American Airlines, Inc. v. Wolens*, 513 U.S. 219 (1995), to suggest that the MDA does not preempt her claims because it "does not require a manufacturer to market any product." Pet. Br. 27. *Wolens* simply concluded that the Airline Deregulation Act, which prohibited States from "enacting or enforcing any law . . . relating to [air carrier] rates, routes, or service," 49 U.S.C. App. § 1305(a)(1) (1988 ed. & Supp. V), did not preempt state-law breach-of-contract actions against an airline because these contractual obligations were self-imposed by the airline, rather than imposed by the State, and the airline could have unilaterally revised its obligations without obtaining regulatory approval. *Wolens*, 513 U.S. at 228-29. In contrast, the design, manufacturing, and labeling requirements to which a PMA-approved device must adhere are imposed by the FDA through its approval of a PMA application, and the manufacturer may not deviate from these requirements without obtaining further FDA approval. 21 U.S.C. § 360e(d)(6)(A)(i).

proval attached to that letter that establishes the specific design, manufacturing, and labeling requirements to which a device is subject. It is the PMA application, as reviewed and approved by the FDA, that sets forth these specifications.

Finally, the fact that the Court held that § 510(k) clearance does not have preemptive effect—even though a manufacturer of a § 510(k)-cleared device may not make changes to that device without obtaining additional FDA approval—has no bearing on whether PMA approval has preemptive force. Clearance under the § 510(k) notification process merely reflects the FDA's conclusion that a device is substantially similar to a device marketed before the enactment of the MDA; it does not embody the FDA's expert regulatory judgment regarding the safety and effectiveness of the product. *See Lohr*, 518 U.S. at 493 (the "510(k) process is focused on *equivalence*, not safety") (internal quotation marks omitted). Thus, under the § 510(k) notification process, the FDA does "not 'require' [a device] . . . to take any particular form for any particular reason." *Id.* at 493. In contrast, when the FDA approves a PMA device, it prohibits modifications to the device's design, manufacturing, and labeling for the very "particular reason" that it has concluded that the device is safe and effective when designed, manufactured, and labeled in accordance with its FDA-approved specifications. The FDA prohibits deviations from those strict specifications because they could compromise the device's safety and effectiveness and imperil the public health.

## II. PETITIONER'S COMMON-LAW CLAIMS SEEK TO IMPOSE STATE-LAW "REQUIREMENTS" "WITH RESPECT TO" THE EVERGREEN BALLOON CATHETER.

The Second Circuit held that, "if successful," petitioner's state-law products liability claims would impose state-law "requirements" regarding the design, manufacturing, and labeling of Medtronic's Evergreen Balloon Catheter. Pet. App. 32a. This conclusion is supported by *Lohr*'s holding that state common-law claims constitute "requirements" under Section 360k(a) and by the fact that petitioner's claims seek to establish a set of "substantive" obligations that are specific to the design, manufacturing, and labeling of the Evergreen Balloon Catheter. *Lohr*, 518 U.S. at 500.

### A. Common-Law Claims Constitute "Requirements" Under Section 360k(a).

Disregarding the clear holding of a majority of the Court in *Lohr*, petitioner contends that state common-law claims can *never* constitute "requirements" under the MDA. Petitioner's argument is at odds with this Court's precedent and the plain language of Section 360k(a).

1. A majority of this Court held in *Lohr* that state common-law claims constitute "requirements" under Section 360k(a). *See* 518 U.S. at 509 (O'Connor, J., concurring in part and dissenting in part, joined by Chief Justice Rehnquist, and Justices Scalia and Thomas) ("state common-law damages actions do impose 'requirements'"); *id.* at 503, 504 (Breyer, J., concurring in part and concurring in the judgment) (expressly "agree[ing]" with Justice O'Connor's "conclusion" that the MDA preempts cer-

tain state-law tort actions). Petitioner concedes this point in discussing *Lohr*. *See* Pet. Br. 9 ("Justice Breyer filed a concurring opinion stating that, in his view, § 360k(a)'s reference to state-law 'requirements' encompasses some state-law damages claims."); *id.* at 10 ("In [Justice O'Connor's] view, state-law damages claims could constitute 'requirements' under § 360k(a)."). Petitioner nevertheless devotes more than eight pages of her brief (at 14-23) to arguing that state common-law claims are not "requirements" under the MDA—without once acknowledging that she is asking this Court to overrule a holding reached by a majority of the Court in *Lohr*.

Petitioner's argument is squarely foreclosed by this Court's precedent, and there is no reason for the Court to revisit this aspect of *Lohr* here. Indeed, this Court has long recognized that damages awards are an effective means of securing regulatory compliance. *See San Diego Bldg. Trades Council v. Garmon*, 359 U.S. 236, 247 (1959) ("[State] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy."). The Court's holding in *Lohr* that state common-law claims can constitute state-law "requirements" under the MDA is consistent with both this well-established principle and with pre-*Lohr* and post-*Lohr* precedent. *See, e.g.*, *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (plurality op.) ("The phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules."); *see also id.* at 548-49 (Scalia, J., concurring in the judgment in part and

dissenting in part) (same). *Lohr*'s holding on this point was recently reaffirmed in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), where the Court held that the term "requirement" in the preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") "reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties." *Id.* at 443.[6]

Any conceivable doubt on this point is dispelled by the regulations that the FDA has promulgated pursuant to the MDA, which explicitly contemplate the preemption of state common-law claims. *See* 21 C.F.R. § 808.1(b) (Section 360k(a) "prescribes a general rule that . . . no State or political subdivision of a State may establish or continue in effect any re-

[6] Petitioner cites this Court's statement in *Bates* that an "event, such as a jury verdict, that merely motivates an optional decision is not a requirement" for preemption purposes. 544 U.S. at 445; *see also* Pet. Br. 12, 39. That statement does not detract from the force of this Court's unambiguous holding in *Bates* that state common-law claims can constitute "requirements." The statement relied upon by petitioner merely rejected the court of appeals' reasoning that a jury verdict that induces a pesticide manufacturer to make the optional decision to alter the labeling or packaging of its product could constitute a "requirement[ ] for labeling or packaging" within the meaning of FIFRA, even if the underlying state-law claim did not actually pertain to the product's labeling or packaging. The Court explained that a requirement "is a rule of law that must be obeyed," rather than an inducement to make an optional decision. *Bates*, 544 U.S. at 445. Here, petitioner's state-law products liability claims, if successful, would impose rules of law that pertain directly to the safety and effectiveness of the Evergreen Balloon Catheter. Indeed, accepting petitioner's reading of this aspect of *Bates* would require this Court to disavow its holdings in both *Bates* and *Cipollone* that state common-law claims—and the jury verdicts to which they may give rise—are "requirements" for preemption purposes.

quirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or *court decision*) . . . .") (emphasis added).

2. Because a majority of this Court has already authoritatively determined that state common-law claims constitute "requirements" under Section 360k(a), this Court need not consider each of petitioner's arguments on this point. *Stare decisis* is sufficient to dispose of all of them. In any event, none of petitioner's three arguments has merit.

Petitioner first contends that the plain language of Section 360k(a) supports the exclusion of common-law claims from the scope of the term "requirement" because the MDA's other references to the term are purportedly limited to positive enactments. The term's other iterations shed no light, however, on whether a state common-law action constitutes a "requirement" under Section 360k(a). Even if petitioner is correct that, as used elsewhere in the MDA, the term is effectively limited to positive enactments, it is the context in which the term is used in these other instances—rather than the definition of the term "requirement" itself—that performs this limiting function.

Section 360k(a), for example, defines preemptive federal "requirements" as "any requirement applicable under this chapter to the device." 21 U.S.C. § 360k(a)(1); *see also id.* § 360k(a)(2) (referring to "a requirement applicable to the device under this chapter"). It is the modifier "applicable under this chapter" that limits preemptive federal requirements to positive enactments, not the definition of the term "requirement." When describing the state laws that Section 360k(a) preempts, however, Congress did not

utilize any limiting modifier at all, but instead gave the term "requirement" its broadest possible reach by extending Section 360k(a) to "*any* requirement." 21 U.S.C. § 360k(a)(1) (emphasis added); *cf.* 5 U.S.C. § 504(a)(4) (referring to "compliance with a statutory or regulatory requirement").

For this same reason, the fact that States may not be able to secure exemptions for state common-law claims under Section 360k(b) merely reflects the fact that it may be exceedingly difficult to demonstrate that a state common-law claim is "more stringent" than a federal requirement or is "required by compelling local conditions." 21 U.S.C. § 360k(b). Although it may not be possible to obtain an exemption for some types of "requirements" under Section 360k(b) due to the exacting prerequisites to securing an exemption, this does not even remotely suggest that the expansive phrase "any requirement" as used in Section 360k(a) does not itself include common-law claims.[7]

Petitioner's reliance on Section 360h(d) of the MDA is similarly misplaced. While Section 360h(d) makes clear that compliance with a repair, replacement, or refund order issued under that section does not "relieve any person from liability under . . . State law," that savings clause does not support petitioner's far-reaching assertion that *all* state common-law claims are outside the scope of the MDA's preemption provision. Section 360h(d) merely suggests that *some* state common-law claims survived the enactment of the MDA—a result fully consistent with the Second

[7] It is therefore irrelevant whether the FDA regulation governing the procedure for obtaining an exemption limits the availability of exemptions to positive enactments. *See* 21 C.F.R. § 808.1(d); Pet. Br. 32.

Circuit's holding that Section 360k(a) preempts state common-law claims that would impose different or additional state-law requirements on PMA-approved devices, but not those "tort claims that are premised on a manufacturer's deviation from the standards set forth in the device's approved PMA application." Pet. App. 36a. *Lohr*'s holding that the MDA does not expressly preempt state-law claims regarding devices that have undergone the § 510(k) notification process creates a further universe of state-law claims that survived the MDA's enactment. The MDA's preemption of state common-law claims that would impose different or additional requirements on PMA-approved devices therefore leaves numerous state-law claims to be "saved" by Section 360h(d).

Finally, petitioner relies on Congress's failure to discuss the preemption issue in the MDA's legislative history as evidence that the statute was not intended to preempt any state common-law claims. But this Court has often warned of the dangers of relying on congressional silence where a statute's meaning is clear from its plain language. *See Whitfield v. United States*, 543 U.S. 209, 216 (2005); *see also Harrison v. PPG Indus., Inc.*, 446 U.S. 578, 592 (1980) ("it would be a strange canon of statutory construction that would require Congress to state in committee reports or elsewhere in its deliberations that which is obvious on the face of a statute"). This Court has recognized that the term "requirement" "easily encompass[es] obligations that take the form of common-law rules." *Cipollone*, 505 U.S. at 521 (plurality op.). As in *Cipollone* and *Bates*—where the Court concluded that Congress intended to preempt state common-law claims without resorting to legislative history—this unambiguous language (rather than ambiguous congres-

sional silence on the topic) should determine the preemptive reach of Section 360k(a).[8]

Indeed, petitioner places far too much weight on the circumstances surrounding Congress's enactment of the MDA. Petitioner asserts, for example, that "for Congress to have preempted damages claims without providing an alternative means of compensation would have been unprecedented." Pet. Br. 18. But that is simply not so. Seven years before the MDA's enactment, Congress amended the Federal Cigarette Labeling and Advertising Act to preempt state-law cigarette advertising "requirement[s] . . . based on smoking and health." 15 U.S.C. § 1334(b). Although Congress did not provide an alternate federal remedy in the statute, this Court held in *Cipollone* that the Labeling Act preempts certain state-law claims against tobacco companies. 505 U.S. at 524, 527 (plurality op.); *see also Pilot Life Ins. Co. v. Dedeaux*, 481 U.S. 41, 55 (1987) (holding that a state-law claim was preempted by the Employee Retirement Income Secu-

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[8] Congress's use of the unambiguous term "requirement" to define the scope of preemption under the MDA also forecloses petitioner's reliance upon the presumption against preemption. Pet. Br. 21-22. As *Cipollone* and *Bates* establish, that general presumption cannot nullify Congress's intention to displace state common-law claims by enacting statutes that preempt state "requirements."

Moreover, the fact that this Court had not yet definitively held that the term "requirement" encompasses state common-law claims when Congress enacted the MDA in 1976 has no more relevance than the presumption against preemption. Pet. Br. 22. The statutes at issue in *Cipollone* and *Bates* were also enacted before this Court had reached such a conclusion. That fact did not carry any weight, however, when the Court construed the term "requirement" in *Cipollone* and *Bates* to reach state common-law claims.

rity Act, even though "the state action purported to authorize a remedy unavailable under the federal provision").

Thus, contrary to petitioner's assertion, it certainly was not "unprecedented" for Congress, at the time it enacted the MDA, to preempt state common-law actions without providing an alternate federal remedy. Moreover, petitioner fails to acknowledge that the class of plaintiffs who are left without any viable cause of action by the preemptive force of Section 360k(a) is exceedingly small because the MDA does not preempt state-law claims regarding § 510(k)-cleared devices or state-law claims alleging that a PMA-approved device failed to comply with a design, manufacturing, or labeling requirement established by the PMA process. As discussed below, Congress made the reasoned determination that preemption of the small category of claims challenging the FDA-approved design, marketing, and labeling of PMA devices would promote the public health by encouraging the development of new life-saving medical technologies. *See infra* Part IV.[9]

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[9] Petitioner also attempts to rely upon the fact that the first PMA preemption cases were not decided until more than a decade after the MDA was enacted to suggest that not even device manufacturers themselves, at the time of the MDA's enactment, considered the possibility that the statute preempted state common-law claims regarding PMA-approved devices. Pet. Br. 22 n.6. But that delay is merely a product of the time that it typically takes to bring a new PMA-approved device to market and the fact that there is generally at least several years between the introduction of a new PMA-approved device and a court decision in a products liability action concerning that device.

### B. Petitioner's Common-Law Claims Would Impose "Requirements" That Are Specific To The Evergreen Balloon Catheter.

Petitioner contends that, even if state common-law claims can constitute "requirements" under Section 360k(a), her claims are not preempted because "the principles of New York law on which [they] rely . . . are principles of 'general applicability' outside the scope of § 360k(a)." Pet. Br. 34-35 (quoting *Lohr*, 518 U.S. at 500) (citations omitted). But an examination of this Court's opinion in *Lohr* and the New York common-law requirements that petitioner is attempting to impose upon the Evergreen Balloon Catheter conclusively establishes that petitioner's causes of action satisfy *Lohr*'s specificity requirement.[10]

1. Section 360k(a) provides that state-law requirements "with respect to a device" are preempted.

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[10] As an initial matter, the plain language of Section 360k(a) does not refer to "specific" state-law requirements, but instead encompasses "any requirement which is different from, or in addition to," a federal MDA requirement. 21 U.S.C. § 360k(a). As Justice O'Connor observed in *Lohr*, "The statute makes no mention of a requirement of specificity, and there is no sound basis for determining that such a restriction on 'any requirement' exists." 518 U.S. at 512 (O'Connor, J., concurring in part and dissenting in part). Thus, to the extent that this Court concludes that petitioner's common-law claims do not satisfy *Lohr*'s specificity requirement, it should reconsider this aspect of *Lohr* and hold—consistent with the plain statutory language—that Section 360k(a) "pre-empts any state common-law action that would impose a requirement different from, or in addition to, that applicable under the FDCA." *Id.* at 511. Petitioner's common-law claims are preempted under that standard because, if successful, they would impose requirements on the Evergreen Balloon Catheter that are different from those established by the FDA through its PMA approval order.

21 U.S.C. § 360k(a). In *Lohr*, this Court concluded that the "general state common-law requirements" that the plaintiffs were attempting to impose upon the defendant's pacemaker "were not specifically developed 'with respect to' medical devices" and therefore were not preempted. 518 U.S. at 501. Although a plurality of the Court thought it "apparent that few, if any, common-law duties have been preempted by" the MDA because "[i]t will be rare indeed for a court hearing a common-law cause of action to issue a decree that has 'the effect of establishing a substantive requirement for a specific device'" (*id.* at 502-03 (quoting 21 C.F.R. § 808.1(d)(6)(ii))), a *majority* of the Court explicitly rejected the notion that state common-law claims would only "rare[ly]" satisfy the specificity requirement. *See id.* at 508 (Breyer, J., concurring in part and concurring in the judgment) ("I am not convinced that future incidents of MDA pre-emption of common-law claims will be 'few' or 'rare.'") (citation omitted); *id.* at 509 (O'Connor, J., concurring in part and dissenting in part) (labeling the plurality's assertion that MDA preemption will be "rare" "bewildering and seemingly without guiding principle").

In his concurrence, Justice Breyer elaborated upon the circumstances in which a state common-law claim would be sufficiently specific to the medical device setting to give rise to preemption under Section 360k(a). He posited a situation where "a federal MDA regulation requires a 2-inch wire, but a state agency regulation requires a 1-inch wire" for a hearing-aid component. *Lohr*, 518 U.S. at 504 (Breyer, J., concurring in part and concurring in the judgment). "If the federal law, embodied in the '2-inch' MDA regulation, pre-empts the state '1-inch' agency regulation," Justice Breyer asked, "why would it not simi-

larly pre-empt a state-law tort action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire (say, an award by a jury persuaded by expert testimony that use of a more than 1-inch wire is negligent)?" *Id.* Justice Breyer recognized that the "effects of the state agency regulation and the state tort suit are identical" and that "[t]o distinguish between them for pre-emption purposes would grant greater power (to set state standards 'different from, or in addition to,' federal standards) to a single state jury than to state officials acting through state administrative or legislative lawmaking processes." *Id.*

Petitioner is asking this Court to draw the exact "distin[ction]" that Justice Breyer—and four other Justices—rejected in *Lohr*. Petitioner is alleging that Medtronic was negligent and is strictly liable under New York law because it designed, manufactured, and labeled the Evergreen Balloon Catheter in conformity with the FDA-approved specifications set forth in its PMA application. If this case reaches trial, petitioner will argue that New York common law required that Medtronic design and manufacture the Evergreen Balloon Catheter in a manner different than that specified in its FDA-approved PMA application and that these alternative design and manufacturing techniques would have prevented the device from rupturing when used during Mr. Riegel's angioplasty. *See* Pet. Br. 11 ("The design-defect claim alleges that the product was not designed adequately to function as intended . . . ."). Petitioner will further argue that New York common law required Medtronic to include a more explicit warning about the risk of rupture and/or more specific instructions for use on the Evergreen Balloon Catheter's label than the warning and instructions ap-

proved by the FDA. *See id.* ("The inadequate warning claim focuses on conflicting information on the label . . . .").

It is the application of these general common-law duties to a specific PMA-approved device that triggers the preemptive effect of Section 360k(a). Indeed, this Court has recognized that "[s]tate power may be exercised as much by a jury's application of a state rule of law in a civil lawsuit as by a statute" or regulation. *BMW of N. Am., Inc. v. Gore*, 517 U.S. 559, 572 n.17 (1996). Thus, "while [a] general [common-law] duty, standing on its own, is not a threat to federal requirements and is not developed specifically 'with respect to' medical devices, the elements needed to prove a violation of that general duty may be very specifically tailored to the device, and the state court action may therefore threaten specific federal requirements." *Martin*, 254 F.3d at 582.

If a jury finds in petitioner's favor in this case, that verdict will be based on the conclusion that New York common-law imposes design, manufacturing, and labeling requirements for the Evergreen Balloon Catheter that are different than those established by the FDA during the PMA process. Those state common-law requirements are just as assuredly "establish[ed] . . . with respect to a device," and are just as assuredly "different from, or in addition to," the requirements established by the FDA, as a set of New York regulations explicitly imposing design, manufacturing, and labeling requirements on balloon catheters. Indeed, whether New York promulgates a regulation requiring balloon catheters to have a rated burst pressure higher than that of the Evergreen Balloon Catheter or a jury finds Medtronic liable under New York common law because it concludes that the Evergreen Balloon Catheter should

have been designed with a higher rated burst pressure, the result would be the same: New York state law would require Medtronic to design, manufacture, and label its device in a manner that diverged from the FDA-approved specifications in its PMA application. *See Cipollone*, 505 U.S. at 521 (plurality op.) ("The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy") (quoting *San Diego Bldg. Trade Council*, 359 U.S. at 247).

Petitioner's common-law claims, if successful, would therefore "have 'the effect of establishing a substantive requirement for a specific device'" (*Lohr*, 518 U.S. at 500), and are preempted by Section 360k(a).

2. The FDA regulations on which petitioner relies do not support a different conclusion. Petitioner invokes 21 C.F.R. § 808.1(d)(1), which provides that Section 360k(a) does not preempt state requirements "of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices." 21 C.F.R. § 808.1(d)(1). This regulation does not—as petitioner contends—limit the preemptive reach of Section 360k(a) to statutory and regulatory requirements that apply specifically and exclusively to medical devices or to common-law causes of action that are applicable only in the device context. Indeed, because there are unlikely to be *any* state common-law causes of action that apply only to medical devices, that reading would essentially nullify the MDA's preemptive effect on state common-law claims—in direct contravention of Congress's inten-

tion to extend Section 360k(a) to "*any* requirement" imposed under state law. *See Lohr*, 518 U.S. at 508 (Breyer, J., concurring in part and concurring in the judgment) ("future incidents of MDA pre-emption of common-law claims will [not] be 'few' or 'rare'") (citation omitted); *cf. Watters v. Wachovia Bank, N.A.*, 127 S. Ct. 1559, 1572 & n.13 (2007) (where a federal statute preempts state law, federal regulations have no bearing on the preemption inquiry).

As the FDA explained at the time it promulgated Section 808.1(d)(1), the regulation was intended to clarify that Section 360k(a) does not preempt state requirements "of general applicability that relate only *incidentally* to medical devices." 42 Fed. Reg. 30,383, 30,384 (June 14, 1977) (emphasis added). A state common-law negligence or strict liability action challenging the design, manufacturing, and labeling of a device is far from only "incidentally" related to that device. If state-law liability is imposed in such a suit, it will be based on a finding that the state common law included a substantive requirement that the device be designed, manufactured, or labeled in a manner different than that approved by the FDA. Unlike requirements that a device comply with the general warranty of fitness—which imposes the same obligation on manufacturers of all products—the parameters of these common-law design, manufacturing, and labeling requirements vary from device to device. A more complex device, for example, may require more extensive labeling than a comparatively more simple device in order to comply with state duty-to-warn standards. Petitioner is therefore seeking to impose a set of common-law requirements on the Evergreen Balloon Catheter that are specific not merely to the medical device context but also to the Evergreen Balloon Catheter itself.

## III. THE STATE-LAW "REQUIREMENTS" THAT PETITIONER SEEKS TO IMPOSE ARE "DIFFERENT FROM" AND "IN ADDITION TO" THE FEDERAL PMA "REQUIREMENTS."

Petitioner's common-law claims allege that the Evergreen Balloon Catheter is defective—even though it was produced in accordance with its FDA-approved design, manufacturing, and labeling specifications. If successful, those claims would therefore impose state-law requirements "with respect to" the Evergreen Balloon Catheter that are "different from," and "in addition to," the federal design, labeling, and manufacturing requirements established through the PMA approval order.

In a final attempt to evade the preemptive reach of Section 360k(a), petitioner nevertheless argues—for the first time in this litigation—that her state-law claims "are based on duties that mirror federal design and labeling requirements" and therefore are not preempted. Pet. Br. 39. Petitioner never argued below that her claims would impose state-law requirements that are equivalent to the federal requirements to which the Evergreen Balloon Catheter must adhere, and this Court therefore need not reach this issue. *See United States v. United Foods, Inc.*, 533 U.S. 405, 416-17 (2001). Indeed, it would be unusual for this Court to delve into the substantive content of New York common law without the benefit of lower-court consideration.[11]

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[11] The only claim that petitioner described below as equivalent to the Evergreen Balloon Catheter's federal requirements was the negligent manufacturing claim—which was dismissed on grounds other than preemption and is not before this Court. Pet. App. 90a.

In any event, petitioner's argument that her state-law claims seek to impose requirements that are parallel to—rather than "different from, or in addition to"—the federal PMA requirements is substantially wide of the mark. In *Lohr*, this Court held that a plaintiff's allegations are not preempted to the extent they "include claims that [the device manufacturer] . . . violated FDA regulations" because those state-law requirements would be "parallel" to the federal requirements. 518 U.S. at 495. In *Bates*, this Court elaborated that a state requirement is parallel to a federal requirement only where the two are "*genuinely* equivalent"—that is, where the defendant is being held liable under state law for conduct that is also prohibited under federal law. 544 U.S. at 454. Other than the no-longer-at-issue negligent manufacturing claim, petitioner has never contended that Medtronic should be held liable under state law because the Evergreen Balloon Catheter did not comply with the federal requirements imposed by the PMA approval order. Petitioner's state-law claims are instead premised on the argument that the device—even when designed, manufactured, and labeled in the manner found to be safe and effective by the FDA—is defective. Far from being "parallel," the state-law requirements that petitioner is seeking to impose are in fact directly at odds with the federal requirements established by the FDA.

Moreover, petitioner is wrong to assert that her state-law failure-to-warn claim is parallel to the MDA's misbranding prohibition. 21 U.S.C. § 352. A plaintiff is barred from pursuing a state-law failure-to-warn claim regarding a device that is labeled in conformity with the requirements of its PMA approval order because such a claim would impermissibly seek to impose state-law labeling requirements

that would be "different from, or in addition to," the federal requirements established by the FDA. The FDA regulations unambiguously confirm that such state-law claims are foreclosed by Section 360k(a). *See* 21 C.F.R. § 808.1(d)(6)(ii) ("Where . . . a prohibition [regarding the manufacture of adulterated or misbranded devices] has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act.").

* * *

Petitioner does not dispute that Medtronic marketed the Evergreen Balloon Catheter in conformity with the specific design, manufacturing, and labeling requirements established by the FDA in its PMA approval order. Because petitioner's state-law claims rest on the premise that the Evergreen Balloon Catheter should have been designed, manufactured, and labeled in a manner different than the one mandated by the FDA, those claims seek to impose state-law requirements "with respect to [the] device" that are "different from" and "in addition to" the device-specific "requirements" established by the FDA and are therefore preempted by Section 360k(a).

## IV. PREEMPTION OF PETITIONER'S STATE-LAW CLAIMS FURTHERS THE OBJECTIVES OF THE MDA.

Through enactment of the MDA, Congress established a uniform federal regulatory framework designed to promote the development, production, and availability of safe and effective medical devices. Preemption of state common-law claims challenging the design, manufacturing, and labeling of PMA-

approved devices promotes this public-health objective by shielding device manufacturers from conflicting regulatory requirements and by preventing lay juries from second-guessing the FDA's expert decision-making through the imposition of potentially crippling state-law liability on manufacturers of devices that the FDA has found to be safe and effective.

A. In order to protect the public from unsafe and ineffective medical devices, the MDA established a comprehensive federal regulatory framework—one aspect of which is the requirement that those devices most likely to pose a risk to the public undergo the rigorous PMA process before reaching the market. At the same time, Congress recognized that imposing overly stringent and potentially conflicting regulatory requirements on the medical device industry could actually undermine the public health by reducing the number of commercially available medical devices. Congress therefore crafted the MDA to be a "balanced regulatory proposal" (H.R. Rep. No. 853, 94th Cong., 2d Sess. 12 (1976)) that promoted medical device safety while ensuring that innovation in the development of life-saving devices was not "stifled by unnecessary restrictions." *Id.* The statute "reflects the need to develop innovative new devices, consistent with the need to protect the subjects of device research." *Id.*

Congress's decision to include an express preemption provision in the MDA that extends beyond positive enactments to state common-law claims was an essential component of its effort to establish a uniform national regulatory framework favorable to technological innovation. As Congress recognized, subjecting manufacturers to a patchwork of overlapping and potentially inconsistent state-law requirements imposed on a case-by-case basis by lay juries

would substantially complicate manufacturers' efforts to develop new devices that complied with all applicable regulatory requirements. *See* H.R. Rep. No. 853, 94th Cong., 2d Sess. 45 (1976) ("[I]f a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened.").

Indeed, this Court has observed that "the rules of law that judges and juries create or apply in [state common-law] suits may . . . create uncertainty and even conflict . . . when different juries in different States reach different decisions on similar facts." *Geier*, 529 U.S. at 871. Subjecting device manufacturers to conflicting state-law obligations would generate widespread regulatory confusion and frustrate attempts to bring new—and potentially life-saving devices—to the market. It is these precise considerations that prompted this Court to conclude that state-law fraud-on-the-FDA claims against medical device manufacturers are impliedly preempted. *See Buckman*, 531 U.S. at 350 ("complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing" medical device manufacturers).

Far from promoting medical devices' safety and effectiveness, superimposing a layer of state-law regulation on top of the federal regulation of PMA-approved devices would actually imperil the public health. PMA-approved devices have been found to be safe and effective by the FDA based on its expert balancing of the risks and benefits presented by the device. 21 U.S.C. § 360c(a)(2)(C). If a jury is permitted to second-guess this expert regulatory judgment by imposing state-law liability based on the performance of a device designed, manufactured, and labeled in

conformity with its PMA requirements, the manufacturer will be placed in the untenable position of having to comply with inconsistent state and federal requirements. If the manufacturer continues to market its device without making alterations to correct the purported "defects" found by the jury, it will expose itself to additional state-law liability. On the other hand, if—to avoid state-law liability—the manufacturer alters the device's design, manufacturing, or labeling, the device will no longer meet the strict conditions of its PMA approval order, and the manufacturer will lack FDA authorization to distribute the modified product. The doctrine of federal preemption—and the MDA's express preemption clause, more specifically—are directed at precisely this type of intolerable conflict between state and federal law. *Cf. Crosby v. Nat'l Foreign Trade Council*, 530 U.S. 363, 378 (2000) (a state "statute conflicts with federal law" where it "penaliz[es] individuals and conduct that [the federal government] has explicitly exempted or excluded from sanctions").

Indeed, lay juries are singularly ill-equipped to evaluate the safety and effectiveness of medical devices, and, for that reason, Congress gave the FDA exclusive responsibility for making such determinations. When the FDA evaluates a device's safety and effectiveness, it takes a broad public health view, balancing not just the risks and benefits that would be experienced by a particular patient, but the risks and benefits that would be experienced by large classes of patients. A jury, in contrast, decides a particular case in isolation, without considering the wider policy implications of its decision. For example, although a jury would consider whether the warning that the plaintiff claims should have been included on a device's label would have prevented

the particular plaintiff's injury, the jury would not consider, and would have no basis for considering, whether inclusion of the warning would unduly detract from more important warnings or unnecessarily deter certain patients from using the device even though they might have benefited from it.[12]

Moreover, the imposition of state-law liability could deter the development of life-saving devices be-

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[12] Petitioner relies on *Bates* to suggest that lay juries should be allowed to nullify the FDA's expert determination that a medical device is safe and effective. *See* Pet. Br. 43. Petitioner's reliance on *Bates* is misplaced because the MDA's regulatory scheme is fundamentally different than the regulatory scheme established by FIFRA, the statute at issue in *Bates*. FIFRA, for example, requires that a pesticide be registered with the FDA before being sold, but "permit[s] the agency to register a pesticide without confirming the efficacy claims made on its label." *Bates*, 544 U.S. at 440. The EPA has "invoked this grant of permission and issued a general waiver of efficacy review." *Id.* As a result, the "EPA's approval of a pesticide label does not reflect any determination on the part of EPA that the pesticide will be efficacious." *Id.* (internal quotation marks omitted). It is therefore quite possibly true that, as *Bates* found, "[b]y encouraging plaintiffs to bring suit for injuries not previously recognized as traceable to pesticides," state-law tort claims "may aid in the exposure of new dangers associated with pesticides." *Id.* at 451 (internal quotation marks omitted). During the PMA process, in contrast, the FDA undertakes a rigorous review of a device's effectiveness (as well as its safety). FDA, Premarket Approval 1. Consequently, state-law tort actions are not necessary to uncover new dangers associated with medical devices. Moreover, the two statutes differ significantly in the role they accord state regulation. FIFRA "authorizes a relatively decentralized scheme that preserves a broad role for state regulation." *Bates*, 544 U.S. at 450. The MDA, however, does not preserve any "concurrent authority of the Federal and State Governments." *Id.* at 451. Indeed, "[u]nder the FDCA, . . . the FDA is vested with centralized authority in order to promote uniformity of regulation." U.S. Cert. Br. 16.

cause manufacturers might be reluctant to expend the necessary tens of millions of dollars in research-and-development funds where the introduction of a new device could potentially result in the imposition of untold amounts of state-law liability. Indeed, many Class III medical devices are invasive products that, in performing their life-saving function, expose patients to some inevitable degree of risk. For many such products, these risks can never be completely eliminated, no matter the rigor of the manufacturer's testing or the amount of resources devoted to research and development. These cutting-edge medical devices—like the Evergreen Balloon Catheter—nevertheless save hundreds of thousands of lives a year, and it is for this reason that the FDA, in its expert judgment, authorizes them to be marketed.

In determining whether to grant PMA approval, the FDA "weigh[s]" these "probable benefit[s] to health from the use of the device against [the] probable risk of injury or illness from such use." 21 U.S.C. § 360c(a)(2)(C). If the FDA determines that—notwithstanding the risks that the device may pose to a small number of patients—the device will be beneficial for the vast majority of patients, the FDA will find the requisite reasonable assurance of safety and effectiveness and will grant the device PMA approval. By definition, this "reasonable assurance" standard contemplates a balancing of risks and benefits to patients, and directly embraces the notion that such devices will not, even when PMA-approved, be *perfectly* safe and effective. Because the FDA's implementation of this careful balancing process cannot be replicated by lay juries, state court proceedings inevitably disrupt the FDA's risk-benefit analysis.

The American Medical Association has recognized the pernicious public-health consequences of

imposing state-law liability on manufacturers of complex medical devices, observing that:

> Product liability is having a profound negative impact on the development of new medical technologies. Innovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance. Certain older technologies have been removed from the market, not because of sound scientific evidence indicating lack of safety or efficacy but because product liability suits have exposed manufacturers to unacceptable financial risks.

Am. Med. Ass'n, *Report of Board of Trustees: Impact of Product Liability on the Development of New Medical Technologies* 1 (1988); *see also* Am. Med. Ass'n, *House of Delegates: Proceedings* 59 (1991) ("The AMA has adopted policy supporting . . . efforts to prevent product liability suits from slowing the development and utilization of medical technologies.").

The important link between preemption protection and the public health is confirmed by the position of the FDA itself, which is entitled to substantial weight in determining the preemptive effect of agency action. *See Geier*, 529 U.S. at 883 ("The agency is likely to have a thorough understanding of its own regulation and its objectives and is 'uniquely qualified' to comprehend the likely impact of state requirements."). The FDA has repeatedly endorsed the position that the MDA preempts state common-law claims regarding PMA-approved devices. *See* Br. for the United States as *Amicus Curiae*, Horn v. Thoratec, 376 F.3d 163 (3d Cir. 2004) (No. 02-4597);

U.S. Cert. Br. 2-3. According to the FDA, exposing manufacturers of PMA-approved devices to state-law liability would "undermine overall public health protection" by interfering with the FDA's expert evaluation of the safety and effectiveness of those devices, by "retarding research and development," and by "encouraging 'defensive labeling' by manufacturers to avoid state liability, resulting in scientifically unsubstantiated warnings and underutilization of beneficial treatments." U.S. *Horn* Br. 3, 26.

Because the imposition of state-law liability on manufacturers of PMA-approved medical devices could decrease the availability of these life-saving devices, it is those patients dependent on such devices for life-sustaining treatment who would suffer most greatly from the distorting effects of unnecessary state regulation.

B. Petitioner's countervailing contention that PMA preemption leaves plaintiffs injured by Class III devices without a remedy is vastly overstated.

First, as the Second Circuit observed, the number of medical devices introduced via the PMA process each year is exceedingly small. Pet. App. 36a. Indeed, in fiscal year 2005, the FDA received 3130 § 510(k) notifications, but only 43 original PMA applications. *See* FDA, 2005 Annual Report 26. Thus, nearly 99% of new Class III medical devices reached the market via the § 510(k) notification process—and that process, this Court concluded in *Lohr*, does not preempt state-law claims. Second, state-law claims based on parallel state-law requirements that are neither "different from" nor "in addition to" those established by the PMA process are not preempted by Section 360k(a), which leaves potential plaintiffs with a state-law remedy for negligent manufacturing

and breach of express warranty, where appropriate. *Lohr*, 518 U.S. at 495. Third, petitioner overlooks the fact that the preemptive effect of the PMA process enhances the safety of medical devices—and reduces the likelihood of personal injury—by affording manufacturers an incentive to subject their products to the rigorous safety-and-effectiveness examination of the PMA process, rather than the substantially more relaxed review of the § 510(k) notification process. If PMA-approved devices became subject to a wide array of state-law products liability claims, there would be substantially less reason for a manufacturer to undertake the costly and time-consuming PMA process for devices that could be cleared pursuant to § 510(k) review.

Preemption of this limited class of claims is thus not only consistent with the MDA's objectives—it is essential to securing the statute's public-health goals.

## CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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IN THE

# Supreme Court of the United States

DONNA S. RIEGEL, individually and
as administrator of the estate of Charles R. Riegel,
*Petitioner*,

v.

MEDTRONIC, INC.,
*Respondent*.

On Writ of Certiorari to the
United States Court of Appeals for the Second Circuit

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## TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ..... ii

INTRODUCTION ..... 1

I. PMA Does Not Establish Device-Specific Requirements That Are Counterparts To Any State-Law Duties Enforced Through Damages Claims. ..... 2

II. The State-Law Duties At Issue Here Are Indistinguishable From The Duties That *Lohr* Held Were Too General To Trigger Section 360k(a). ..... 11

III. Ms. Riegel's State-Law Claims Are Based On Duties That Parallel Federal Requirements. ..... 13

IV. The Background, Structure, and Purpose of the MDA Demonstrate That Section 360k(a) Does Not Broadly Preempt Damages Claims. ..... 15

CONCLUSION ..... 20

## TABLE OF AUTHORITIES

**CASES** Page

*Agostini v. Felton*,
521 U.S. 203 (1997) ..... 12

*Alexander v. Sandoval*,
532 U.S. 275 (2001) ..... 12

*Bates v. Dow AgroSciences*,
544 U.S. 431 (2005) ..... 11, 13, 15, 16

*Blunt v. Medtronic, Inc.*,
2007 WL 2176136 (Wis. App. 2007) ..... 4

*Bowling v. Pfizer*,
143 F.R.D. 141 (S.D. Ohio 1992) ..... 1, 16, 19

*Buckman v. Plaintiffs Legal Committee*,
531 U.S. 341 (2001) ..... 10

*Cipollone v. Liggett Group, Inc.*,
505 U.S. 504 (1992) ..... 16, 18

*Commissioner v. Lundy*,
516 U.S. 235 (1996) ..... 17

*Donnely v. Copeland Intra Lenses, Inc.*,
87 F.R.D. 80 (E.D.N.Y. 1980) ..... 1

*Freightliner Corp. v. Myrick*,
514 U.S. 280 (1995) ..... 9

*Goodlin v. Medtronic, Inc.*,
167 F.3d 1367 (11th Cir. 1999) ..... 1

*In re Guidant Corp. Implantable Defibrillators Products Liability Litigation*, MDL No. 05-1708,
2007 WL 2071804 (D. Minn. July 16, 2007) ..... 1

*In re Guidant Corp. Implantable Defibrillators Products Liability Litigation*, MDL No. 05-1708,
2007 WL 1725289 (D. Minn. June 12, 2007) ..... 19

*Horn v. Thoratec Corp.*,
376 F.3d 163 (3d Cir. 2004) ..... 19

*Kemp v. Medtronic, Inc.*,
231 F.3d 216 (6th Cir. 2000) ..... 19

*Kennedy v. Collagen Corp.*,
67 F.3d 1453 (9th Cir. 1995) ..... 1

*Kernats v. Smith Industries Medical Systems, Inc.*,
669 N.E.2d 1300 (Ill. App. 1996) ..... 1

*Khan v. Shiley, Inc.*,
266 Cal. Rptr. 106 (Cal. Ct. App. 1990) ..... 16

*Maryland v. Wilson*,
519 U.S. 408 (1997) ..... 12

*United States v. Mead Corp.*,
533 U.S. 218 (2001) ..... 11

*In re Medtronic Implantable Defibrillators* (MDL),
465 F. Supp. 2d 886 (D. Minn. 2006) ..... 3, 19

*Medtronic, Inc. v. Lohr*,
518 U.S. 470 (1996) ..... *passim*

*Michael v. Shiley, Inc.*,
46 F.3d 1316 (3d Cir. 1995) ..... 16

*National Bank of Commerce of El Dorado v. Kimberly-Clark*, 38 F.3d 988 (8th Cir. 1994) ..... 14

*Nelson v. Adams USA, Inc.*,
529 U.S. 460 (2000) ..... 13

*Niehoff v. Surgidev*,
950 S.W.2d 816 (Ky. 1997) ..... 1

*Norfolk Southern Railway Co. v. Shanklin*,
529 U.S. 344 (2000) ..... 11

*Puerto Rico Department of Consumer Affairs v. ISLA Petroleum Corp.*, 485 U.S. 495 (1988) ..... 9

*Rice v. Norman Williams Co.*,
458 U.S. 654 (1982) ..... 9

*Sowell v. Bausch & Lomb, Inc.*,
230 A.D.2d 77 (N.Y. App. Div. 1997) ..... 3

*Sprietsma v. Mercury Marine*,
537 U.S. 51 (2002) ..... 9, 16

*Travelers Casualty & Surety Co. v. Pacific Gas & Electric Co.*, 127 S. Ct. 1199 (2007) ..... 13

*Webster v. Pacesetter, Inc.*,
171 F. Supp. 2d 1 (D.D.C. 2001) ..... 3

*Weiland v. Telectronics Pacing System, Inc.*,
721 N.E.2d 1149 (Ill. 2000) ..... 1

**STATUTES**

21 U.S.C. § 331(a) ..... 6

21 U.S.C. § 352(a) ..... 6

21 U.S.C. § 360(h) ..... 7

21 U.S.C. § 360(j)(l) ..... 16

21 U.S.C. § 360c(a)(1)(C) ..... 13

21 U.S.C. § 360e(b)(1) ..... 19

21 U.S.C. § 360e(i) ..... 20

21 U.S.C. § 360h ..... 14

21 U.S.C. § 360k(a) ..... *passim*

29 U.S.C. § 1132(a)(1)(B) ..... 19

45 U.S.C. § 434 (1970),
*recodified as amended at* 49 U.S.C. § 20106. ..... 19

**REGULATORY MATERIALS**

21 C.F.R. § 801.109 ..... 6

21 C.F.R. § 803.50 ..... 7, 14

21 C.F.R. § 807.81(a)(3)(i) ..... 6

21 C.F.R. § 807.81(a)(3)(ii) ..... 6

21 C.F.R. § 807.87(e) ..... 6

21 C.F.R. § 808.1 ..... 17

21 C.F.R. § 808.1(d) ..... 8, 10, 11, 17

21 C.F.R. § 810.10 ..... 14
21 C.F.R. § 814.39 ..... 6, 14
21 C.F.R. § 814.39(d) ..... 3, 5, 6
21 C.F.R. § 814.39(d)(2) ..... 5
21 C.F.R. § 814.44(e) ..... 9
21 C.F.R. § 814.84(b) ..... 7, 14
21 C.F.R. Part 820 ..... 7
21 C.F.R. § 886.3600 ..... 16
43 Fed. Reg. 18661 (1978) ..... 8, 9, 17
45 Fed. Reg. 67321 (1980) ..... 8

**MISCELLANEOUS**

FDA, Database listing PMA submissions, www.fda.gov/cdrh/pmapage.html#pma (pma.zip) ... 20

FDA, Database listing 510(k) submissions, 1996-current, www.fda.gov/cdrh/510khome.html (PMN96CUR.ZIP) ..... 20

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FDA, *Deciding When to Submit a 510(k) For a Change to an Existing Device* (Jan. 1997), www.fda.gov/cdrh/ode/510kmod.html ..... 6

FDA, *Device Advice—Premarket Approval (PMA)*, www.fda.gov/cdrh/devadvice/pma/printer.html (last updated Dec. 21, 2004) ..... 6

B. Feder, *Patients Warned as Maker Halts Sale of Heart Implant Part*, N.Y. Times, Oct. 15, 2007 ..... 15

H.R. Rep. No. 94-853 (1976) ..... 14

Restatement (Third) of Torts: Products Liability (1998) .. 15

## INTRODUCTION

Throughout their briefs, Medtronic and its amici speak as if the traditional state-law civil justice system did not exist. They talk about what "would" happen if damages claims "could" proceed against manufacturers of medical devices that received premarket approval ("PMA") from the Food and Drug Administration ("FDA"). This purported concern need not worry us here because damages claims against manufacturers of PMA devices are not new remedies that the Court is being asked to create. Damages claims pre-existed the Medical Device Amendments of 1976 ("MDA") and have co-existed with PMA for 30 years since then. Medtronic and its amici offer no evidence that manufacturers have had difficulty complying with federal device requirements while also being held accountable to patients under state law for injuries caused by their products.[1]

In essence, Medtronic's argument consists of the mantra that PMA transforms a manufacturer's device design and labeling into federal requirements. That argument misconceives the nature of PMA, which allows a manufacturer to sell a particular device but does not impose federal design and labeling specifications. Thus, no federal design or labeling specifications exist for the type of catheter at issue here. The PMA permitted Medtronic to market a balloon catheter with the

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[1]Although many tort cases settle without a court decision, the number of reported cases involving PMA devices is nonetheless significant. *See, e.g., Goodlin v. Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999); *Kennedy v. Collagen Corp.*, 67 F.3d 1453 (9th Cir. 1995); *In re Guidant Corp. Implantable Defibs. Prods. Liab. Litig.*, MDL No. 05-1708, 2007 WL 2071804 (D. Minn. July 16, 2007); *Bowling v. Pfizer*, 143 F.R.D. 141 (S.D. Ohio 1992); *Donnely v. Copeland Intra Lenses, Inc.*, 87 F.R.D. 80 (E.D.N.Y. 1980); *Weiland v. Telectronics Pacing Sys., Inc.*, 721 N.E. 2d 1149 (Ill. 2000); *Niehoff v. Surgidev*, 950 S.W.2d 816 (Ky. 1997); *Kernats v. Smith Indus. Med. Sys., Inc.*, 669 N.E. 2d 1300 (Ill. App. 1996).

particular design and label that injured Mr. Riegel, but Medtronic was not required to choose those specifications. If Medtronic chooses to market a balloon catheter, it can select any of the several designs and labels for which it has obtained approval, or, if it is unsatisfied with those, obtain approval for new ones.

Medtronic's argument also ignores important elements of the federal regulatory scheme, such as the regulations allowing manufacturers to alter labeling to enhance patient safety. In addition, the federal labeling requirements applicable to Medtronic's PMA device were substantially the same as those at issue in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). The Court has already held that those requirements do not reflect "the sort of concerns regarding a specific device or field of device regulation that the statute or regulations were designed to protect from potentially contradictory state requirements." *Id.* at 501.

Finally, to prevail here, Medtronic must show not only a device-specific federal requirement, but also a counterpart state requirement. Medtronic's brief fails to distinguish—indeed it makes little effort to distinguish—the state-law duties here from those found too general to warrant preemption in *Lohr*.

## I. PMA Does Not Establish Device-Specific Requirements That Are Counterparts To Any State-Law Duties Enforced Through Damages Claims.

The parties agree that the PMA process can be demanding and time-consuming. However, when the process is complete and the FDA grants PMA, the requirements imposed on the manufacturer generally are neither "specific" to the device nor counterparts to any "different" or "additional" state requirement relevant here, as required for preemption under 21 U.S.C. § 360k(a). *See Lohr*, 518 U.S. at 200-01.

**A.** Medtronic's response to this point is twofold. First, the company emphasizes the rigor of PMA review. Medtronic never explains, however, how the number of hours that the

FDA spends making a PMA determination relates to the question of preemptive requirements under § 360k(a). The PMA route to marketing differs from the 510(k) route. But the relevant question is not what steps a manufacturer must take to get a product to market. The question is what requirements are imposed as a result of taking those steps and, as to each such requirement, whether it is "'specific' to a 'particular device'" or has a "specific counter-part" in state law. *Lohr*, 518 U.S. at 500 (quoting 21 C.F.R. § 808.1(d)). The rigor of the PMA review process does not answer these questions. *See Webster v. Pacesetter, Inc.*, 171 F. Supp. 2d 1, 11 (D.D.C. 2001) ("[I]t is the specificity of the regulatory mandate, not the length and cost of review, that is relevant under Section 360k."); *Sowell v. Bausch & Lomb, Inc.*, 230 A.D.2d 77, 84 (N.Y. App. Div. 1997) ("[W]hile a PMA review is considerably more rigorous and detailed than the premarket notification at issue in [*Lohr*], it is, in fact, no more 'specific' a requirement.").

Next, Medtronic argues that when the FDA grants PMA, it imposes a number of requirements on the design and labeling of the device. Thus, Medtronic states (at 17) that "the manufacturer may market the device *only* as specified in the PMA application." Yet at the same time, Medtronic acknowledges that a manufacturer may alter the design or labeling, with FDA approval. *See also* 21 C.F.R. § 814.39(d) (listing labeling changes that may be made without pre-approval). Thus, a manufacturer can market a particular device or type of device using any number of designs and labels, at its own choosing.

Recent cases involving injuries caused by another PMA device offer a real-world illustration of this point. In December 2002, the FDA granted PMA to a Medtronic implantable defibrillator. In January 2003, Medtronic identified a design defect that could cause the battery to fail. Medtronic then sought and obtained approval for three additional models that used the same battery, never advising the FDA of the serious problem. *In re Medtronic Implantable Defibs.* (MDL), 465 F. Supp. 2d 886, 889 (D. Minn. 2006). In October 2003,

Medtronic filed a PMA supplement seeking approval for design changes to improve the defective battery used in the various defibrillators, and the FDA granted the supplemental PMA later that month. Medtronic then sold the devices with both the old, defective design and the new, improved design. *Blunt v. Medtronic, Inc.*, 2007 WL 2176136, ¶¶ 2-3 (Wis. App. 2007). Although Medtronic knew that the older model had a design flaw, it wanted to use up its inventory. *Id.* ¶ 22 (Fine, J., dissenting).

The facts surrounding this device differ from the facts presented here, but Medtronic's theory would require the same outcome in each case. In lawsuits seeking damages for injuries caused by the defective defibrillators, including those implanted *after* the safer model had been approved, Medtronic has argued that PMA of the original design constituted a "specific federal requirement" for purposes of § 360k(a), *see Blunt*, 2007 WL 2176136, ¶ 13, even though the company had already redesigned the product to correct a dangerous defect and was already marketing the redesign. And if it were true that PMA constituted a specific design and labeling requirement for purposes of § 360k(a), then the PMA's preemptive effect would continue even after the company had redesigned the product, as long as the FDA had not withdrawn PMA (an unusual occurrence). Yet if the company were subject to a "specific federal requirement" that its defibrillator have the original design, how could it also be subject to a "specific federal requirement" that the defibrillator have the revised design? The answer is that it cannot. The company is permitted to sell products with either design because PMA is a marketing license, *allowing* a company to market a product with a particular design, but not *requiring* it to market the product with that design as opposed to any other approved (or approvable) design. The requirement is that the manufacturer obtain permission to market its product, not that it design the product in any particular way. Thus, Medtronic marketed the catheter at issue in this case first with one design and later with

others, as it twice submitted PMA supplements concerning design changes. JA 16, 26.

Moreover, Medtronic does not even mention 21 C.F.R. § 814.39(d). Under that regulation, manufacturers of PMA devices may strengthen a contraindication, precaution, or warning; strengthen an instruction intended to enhance the safe use of the device; and delete misleading or false statements from the label, *without* prior FDA approval. *Id.* § 814.39(d)(2).

The United States recognizes that § 814.39(d) belies the argument that PMA establishes preemptive labeling requirements. It suggests, first, that the sorts of changes allowed under this regulation "do not appear to apply here." US Br. 13-14. That suggestion is incorrect because Ms. Riegel's failure-to-warn claim is based on the inadequacy of the warnings, precautions, and instructions. *See* Pet. Br. 11, 42-43. The United States then notes that, pursuant to a draft guidance document issued earlier this year, changes under § 814.39(d) must be based on "newly-acquired safety-related information" "not previously considered by the FDA." US Br. 14 (quoting www.fda.gov/cdrh/ode/guidance/1584.pdf ("March 2007 Guidance")). Even if the guidance were binding, *but see* March 2007 Guidance at 1 (guidance "does not operate to bind FDA or the public"), and even if it applied to a defect identified in the 1990s in a device no longer on the market, the guidance would have permitted Medtronic to make changes based on "newly-acquired" information derived from post-approval adverse event reports. In any event, although some labeling changes require FDA pre-approval, a manufacturer that never sought to make and was never denied permission to make a relevant change cannot rightly invoke the pre-approval requirement as a bar to state-law liability.

**B.** As the parties have explained, PMA represents the FDA's determination that a manufacturer has demonstrated that a device offers a "reasonable assurance of safety and effectiveness." The consequence of this determination is, "in effect, a private license granting the applicant (or owner) permission to

market the device." FDA, *Device Advice—Premarket Approval (PMA)*, www.fda.gov/cdrh/devadvice/pma/printer.html at 1 ("*Device Advice*"). Medtronic is correct that, as long as the manufacturer chooses to market that version of the device, it must comply with various conditions imposed by the license. However, the requirements imposed are no more specific than the requirements imposed on the 510(k) device at issue in *Lohr*. In fact, many are the same.

For example, whether marketing permission is obtained via the PMA process or the 510(k) process, the manufacturer cannot make design changes that affect the safety or effectiveness of the device without FDA's permission. *Compare* 21 C.F.R. § 814.39 (PMA supplements), *with id.* at § 807.81(a)(3)(i) (new 510(k) submissions). With respect to labeling, the federal requirements are almost identical. The regulation that governs the content of prescription device labeling, 21 C.F.R. § 801.109, applies to both PMA and 510(k) devices. And both PMA and 510(k) labels cannot be "false or misleading in any particular." 21 U.S.C. §§ 331(a), 352(a). Medtronic suggests (at 21) that the requirements imposed with respect to its catheter were more "specific" than those imposed on the pacemaker lead in *Lohr* because the catheter's label had to adhere to the approved labeling. However, proposed labeling must be included in the marketing application for both PMA and 510(k) devices. *See* 21 C.F.R. § 807.87(e) (510(k) submission requirements). And many post-marketing labeling changes for both PMA and 510(k) devices require approval, either in advance of making the change or after the fact. *See id.* § 814.39(d) (listing changes to PMA device labels that may be made without preapproval); *id.* § 807.81(a)(3)(ii) (labeling change requiring submission of new 510(k)); FDA, *Deciding When to Submit a 510(k) For a Change to an Existing Device* 9-12 (Jan. 1997), www.fda.gov/cdrh/ode/510kmod.html (listing changes to 510(k) device labels that require new 510(k) submissions).

Medtronic's argument is at heart that an FDA finding that a device presents reasonable assurance of safety and effectiveness should preempt a state-law damages remedy for design defect or inadequate labeling. That argument has no support in § 360k(a), which looks not to federal "findings" but to counterpart state and federal "requirements." The question is not what the FDA has found, but what the FDA has required.

**C.** Medtronic takes issue (at 19 n.3) with amicus AARP's characterization of PMA as a "one-time licensing scheme." The FDA itself, however, describes PMA as a "license." *Device Advice* at 1. In any event, Medtronic's response to the AARP shows that, although regulation continues after the FDA grants PMA, post-approval oversight is strikingly similar for PMA and 510(k) devices. Medtronic first states that manufacturers of PMA devices must inform the FDA of adverse events associated with approved devices, but that obligation applies to *all* manufacturers, regardless of the route that the device took to get to the market. *See* 21 C.F.R. § 803.50. Citing 21 U.S.C. § 360(h), Medtronic also notes that the FDA may undertake periodic inspections of PMA manufacturing facilities, but that regulation also applies to both PMA and 510(k) devices. *See also* 21 C.F.R. Part 820 (good manufacturing practices regulations applicable to all devices). And Medtronic cites the FDA's power under 21 U.S.C. § 360h to order a manufacturer to repair, replace, recall, or cease distribution of a device. Again, that provision applies to all devices, not only to PMA devices. In the end, the only requirement that Medtronic identifies that concerns PMA devices but not 510(k) devices is the submission of an annual report summarizing studies concerning the device. *See* 21 C.F.R. § 814.84(b). That requirement, however, does not relate to any aspect of device design or labeling and provides no basis for distinguishing this case from *Lohr*.

**D.** Medtronic states (at 22, 23) that Ms. Riegel has insisted that *only* FDA *regulations* can have preemptive effect under § 360k(a) and that PMA "does not have preemptive effect."

These characterizations of Ms. Riegel's argument are wrong. *See* Pet. Br. 25 ("The Riegels agree that PMA may have a preemptive effect."). Simply saying that PMA is preemptive, however, begs the question of what PMA preempts. *See also* Chamber of Commerce Br. 21 (arguing that Congress intended PMA to preempt but failing to consider *what* Congress intended it to preempt). Under § 360k(a), as construed in both *Lohr*, 518 U.S. at 500, and 21 C.F.R. § 808.1(d), preemption turns on counterpart state and federal requirements. Thus, once the FDA calls for PMA for a device, any state premarket approval requirement is preempted. But product liability claims for design defect or failure to warn are not counterpart requirements to PMA--they do not address the same topic (marketing approval)—and thus they are not preempted by PMA. Before 2003, the FDA understood § 360k(a) in just this way. *See, e.g.*, 45 Fed. Reg. 67321, 67323 (1980); 43 Fed. Reg. 18661, 18664 (1978); Br. of US as Amicus Curiae at 14-17, *Smith Indus. Med. Sys. v. Kernats*, 522 U.S. 1044 (1998) (No. 96-1407) ("U.S. *Kernats* Br."). This understanding of § 360k(a)—that it requires subject matter overlap between the federal and state laws—is also reflected in Justice Breyer's concurrence in *Lohr*, which posited that an FDA regulation that required 2-inch hearing aid wires would preempt a state regulation requiring 1-inch wires, but would not preempt state hearing aid rules addressing other aspects of the device, such as rules relating to packaging. 518 U.S. at 504, 505.

Accordingly, Medtronic's argument (at 21 n.4) that it cannot be held liable for failing to warn through a "Dear Doctor" letter because federal law allows but does not require manufacturers to send Dear Doctor letters must fail. Because federal law does not impose requirements with regard to Dear Doctor letters, a failure-to-warn claim based on the company's failure to send a letter clarifying the instructions for use or strengthening the warnings has no federal counterpart. It thus is not preempted by § 360k(a). *See Lohr*, 518 U.S. at 494 (where no design requirement in effect, § 360k(a) does not preempt design claim); 21 C.F.R. § 808.1(d) (state requirements

preempted "when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to the device under the act"); 43 Fed. Reg. 18663 (state device laws not preempted until such time as FDA implements counterpart federal requirements).

Medtronic (at 23-24) likewise takes issue with the distinction between PMAs granted on the condition that the product comply with device-specific requirements issued under 21 C.F.R. § 814.44(e), and PMAs granted without such specific conditions. *See* US Br. 15 (making same argument). Medtronic professes to find the distinction unsupportable, yet it flows directly from § 360k(a) and the FDA's implementing regulations, which premise preemption on device-specific requirements. *Cf. Puerto Rico Dep't of Consumer Affairs v. ISLA Petroleum Corp.*, 485 U.S. 495, 503 (1988) ("There is no federal pre-emption *in vacuo*, without a congressional text or a federal statute to assert it.") Although § 814.44(e) gives the FDA some authority to impose specific design and labeling requirements through the PMA process, the authority to impose requirements is not equivalent to the exercise of that authority. *See Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002) (decision not to issue regulation requiring design feature does not pre-empt damages claims based on injury caused by failure to install that feature); *Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995) (same); *cf. Rice v. Norman Williams Co.*, 458 U.S. 654, 659 (1982) ("The existence of a hypothetical or potential conflict is insufficient to warrant pre-emption of a state statute."). As the United States previously explained to the Court:

> If (as in this case) the FDA has not set out specific federal requirements for the particular device, the manufacturer may select any design, manufacturing, or labeling features that will satisfy the general minimum standards in the Act and regulations, and it may obtain . . . PMA on the basis of that selection if the FDA approves the application. Because the FDA has not imposed any specific substantive requirements on

> petitioner's design of the [device at issue] in the course of the review process, that design does not represent a specific federal requirement that preempts state common law requirements.

U.S. *Kernats* Br. 16. Review of current FDA regulations shows that, as the United States represented to the Court in 1997, the FDA "imposes such specific requirements on Class III devices only in extraordinary circumstances." *Id.* at 15. For these reasons, preemptive requirements applicable to Medtronic's catheter did not flow from the PMA itself.

**E.** In 1996 in *Lohr*, in 1997 in *Kernats*, and in 2000 in *Buckman v. Plaintiffs Legal Committee*, 531 U.S. 341 (2001), the FDA filed briefs in this Court arguing for a narrow construction of § 360k(a) that reflected the approach of the FDA's regulation, 21 C.F.R. § 808.1(d). In the most recent of the three briefs, the agency described *Lohr*'s holding with approval and in a manner consistent with Ms. Riegel's reading, calling it a "sensible and administrable line" for determining the kind of federal requirements that "can have preemptive force" under § 360k(a). Br. of US as Amicus Curiae at 12, *Buckman v. Plaintiffs Legal Committee*, 531 U.S. 341 (2001) (No. 98-1768). Citing regulations that establish specific labeling, testing, or performance standards for particular devices, the United States explained that these kinds of FDA requirements preempted different or additional "counterpart state requirements" because the "federal requirements are stated with specificity and apply to a specific device or set of devices." *Id.* In contrast, FDA's "labeling requirements do not have preemptive force" because they "are stated at a high level of generality and apply to all devices." *Id.*

The United States has now done an about-face with respect to the preemptive scope of PMA, as its brief in this case (at 24) concedes. Nonetheless, the United States asks for deference to its current view. Deference is unwarranted. In *Lohr*, the Court gave "substantial weight" to FDA regulations issued after notice-and-comment rulemaking, 518 U.S. at 496, not to the

United States's brief, and those regulations have not changed. Notably, the United States's amicus brief at the petition stage in this case, which primarily made a merits argument, did not even cite the preemption regulations. And its brief at the merits stage relies on them only sparingly. *See* US Br. 15, 27, 28.[2] For this reason, "[a]lthough generally 'an agency's construction of its own regulations is entitled to substantial deference,' *Lyng v. Payne*, 476 U.S. 926, 939 (1986), no such deference is appropriate," or even comes into play, with respect to the agency's view here because it exists apart from and in contradiction with the regulations. *Norfolk S. Ry. Co. v. Shanklin*, 529 U.S. 344, 356 (2000); *see United States v. Mead Corp.*, 533 U.S. 218, 228 (2001) (degree of deference due to government depends on, among other things, consistency and formality of government's position).

To the extent that the agency's view as expressed in 21 C.F.R. § 808.1(d) informed the Court's construction of § 360k(a) in *Lohr*, it should do so here as a matter of stare decisis. At the same time, in light of the agency's complete reversal on a question of statutory interpretation and the fact that the Court has before it a precedent construing that statute, the views expressed in the United States's latest amicus brief deserve no weight. *Cf. Bates v. Dow AgroSciences*, 544 U.S. 431, 449, 451-52 (2005) (giving no weight to agency's view of preemption in light of agency's reversal).

## II. The State-Law Duties At Issue Here Are Indistinguishable From The Duties That *Lohr* Held Were Too General To Trigger Section 360k(a).

In *Lohr*, the Court held that the common-law duties at issue in that lawsuit did not trigger § 360k(a). The majority opinion explained that such "general" state requirements "are not the kinds of requirements that Congress and the FDA feared would

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[2]The United States's brief also cites § 808.1(d) as background (US Br. 4, 5, 9, 11) and for an uncontested point (*id.* at 20).

impede the ability of federal regulators to implement and enforce specific federal requirements." 518 U.S. at 501. For example, "the predicate for the failure to warn claim" alleged by the Lohrs was "the general duty to inform users and purchasers of potentially dangerous items of the risks involved in their use." *Id.* The Court stated that "[t]hese general obligations are no more a threat to federal requirements than would be a state-law duty to comply with local fire prevention regulations and zoning codes, or to use due care in the training and supervision of the work force." *Id.* at 501-02. The conclusion that the "generality" of the state-law duties at issue "leaves them outside the category of requirements that § 360k envisioned to be 'with respect to' specific devices," *id.* at 502, is a holding of *Lohr*.

If merely enforcing a general state-law duty in a device case transformed that duty into a device-specific requirement, then *Lohr*'s discussion of this point would have been unnecessary. Medtronic, however, puts *Lohr*'s holding to the side and argues (at 35-36) that Ms. Riegel's claims are preempted under Justice Breyer's concurrence. First, under basic principles of stare decisis, a separate concurrence, regardless of its content, does not alter the meaning of a majority opinion of this Court. *Alexander v. Sandoval*, 532 U.S. 275, 285 n.5 (2001); *see Maryland v. Wilson*, 519 U.S. 408, 413 (1997) (concurring opinion does not establish precedent); *see also Agostini v. Felton*, 521 U.S. 203, 217 (1997) (state of the law not affected by views of five Justices in concurring opinions).

Second, Ms. Riegel's damages claims, based on general state-law duties with respect to the design and labeling of dangerous products, do not involve specific state-law requirements of the "2-inch wire" variety described in Justice Breyer's concurrence, any more than did the claims presented in *Lohr*. In fact, the entirety of Medtronic's argument on this point would be equally applicable to the state-law duties in *Lohr*, yet a majority of the Court, including the concurring Justice, rejected that theory. On the state-law side of the pre-

emption analysis, there is no difference between this case and *Lohr*.[3]

## III. Ms. Riegel's State-Law Claims Are Based On Duties That Parallel Federal Requirements.

This Court has unanimously held that state-law requirements that parallel federal requirements do not fall within the preemptive scope of § 360k(a). *Lohr*, 518 U.S. at 495; *id.* at 513 (O'Connor, J., concurring in part and dissenting in part); *see also Bates*, 544 U.S. at 447-48 (citing *Lohr*). Ms. Riegel's claims are therefore not preempted to the extent that they are premised on state-law requirements that parallel requirements imposed under the MDA.

Medtronic first tries to avoid the point by asserting (at 40) that Ms. Riegel waived any argument based on *Lohr*'s unanimous identity-of-requirements holding by not making the argument below. However, *Lohr*'s holding cannot be so easily side-stepped. To begin with, Ms. Riegel's opening brief in the court of appeals did make this point. *See* Appellants' Br. 31 (arguing that warning claim parallels requirements of 21 C.F.R. § 814.39(d)). Moreover, although this Court generally will not consider *issues* neither raised nor decided below, *Travelers Cas. & Sur. Co. v. Pacific Gas & Elec. Co.*, 127 S. Ct. 1199, 1207 (2007), Ms. Riegel's argument on this point does not raise a new issue. Below, she argued both that federal requirements do not preempt her claims and that *Lohr* supports her argument. Highlighting a particular paragraph of *Lohr* is not raising a new "issue." *See also Nelson v. Adams USA, Inc.*, 529 U.S. 460, 469 (2000) (issue preservation "does not demand the incantation of particular words; rather, it requires that the lower court

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[3]Amicus Chamber of Commerce (at 11-12) argues at length that it would not make sense to hold that common-law claims are not preempted but that state statutes codifying the common law are preempted. Ms. Riegel has not drawn that distinction. Her point is that § 360k(a) does not preempt damages claims based on state-law duties of general applicability.

be fairly put on notice as to the substance of the issue"); *National Bank of Commerce of El Dorado v. Kimberly-Clark*, 38 F.3d 988, 992 n.2 (8th Cir. 1994) (where complaint alleges failure to warn, argument that defendant did not comply with FDA regulations is not a new argument, but a standard by which to measure defendant's conduct).[4]

Turning to the merits, Medtronic contends (at 41) that a design defect or inadequate labeling claim is "directly at odds" with federal requirements because, through PMA, the FDA "found [the device] to be safe and effective." PMA, however, is not a finding that a device *is* safe and effective, but that the application presents "reasonable assurance" of safety and effectiveness. 21 U.S.C. § 360c(a)(1)(C). The statute and regulations recognize that the FDA's finding that a device carries "reasonable assurance" of safety and effectiveness may be wrong, either initially or because of later advances in technology. *See* H.R. Rep. No. 94-853 at 23, 32 (1976) (discussing patient notification and PMA withdrawal provisions). For example, as noted above, FDA regulations set forth procedures for manufacturers to revise PMA design and labeling to enhance safety or effectiveness. 21 C.F.R. § 814.39. In addition, manufacturers must submit adverse event reports to the FDA, *id.* § 803.50 (applicable to all devices), and an annual report of clinical and nonclinical studies, *id.* 814.84(b), to allow the FDA continually to reassess the risk/benefit determination made through the PMA process. Further manifesting that PMA is not a federal finding that a product is not defective, the FDA may order a PMA device (or any device) recalled or repaired. 21 U.S.C. § 360h; 21 C.F.R. § 810.10.

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[4]In contrast, Washington Legal Foundation's argument that the MDA *impliedly* preempts damages claims presents an issue neither raised nor decided below. Moreover, implied preemption is not fairly encompassed in the question presented, which asks "[w]hether the *express preemption provision* of the [MDA], 21 U.S.C. § 360k(a), preempts state-law claims ." Pet. i (emphasis added).

And, of course, the manufacturer is free to recall or discontinue a defective device, without running afoul of the PMA determination. *See, e.g.*, B. Feder, *Patients Warned as Maker Halts Sale of Heart Implant Part*, N.Y. Times, Oct. 15, 2007 (describing recent Medtronic recall).

In light of the many statutory and regulatory provisions premised on and reiterating that a PMA device may prove to be defective, Medtronic's simplistic argument—essentially, that if the FDA granted PMA, then the product is safe—falls well short of demonstrating that the state-law duties at issue (*see* Pet. Br. 40-42) are not parallel to federal requirements. Moreover, Medtronic does not even attempt a response to Ms. Riegel's discussion of the parallel between the federal labeling requirements and the state-law inadequate labeling claim.

Taking a more realistic stance, the United States says (at 23 n.4) that an existing PMA "strongly suggests" that a device is not defective. This statement reflects that PMA is best considered as a defense on the merits, not as a "get-out-of-jail-free card" precluding consideration of the merits. The usual common-law rule is that compliance with a safety statute or regulation is relevant in a products liability case to "suggest" that the product is not defective, but does not preclude a finding of defect. *See* Restatement (Third) of Torts: Prods. Liab. § 4(b) & Reporters' Note, comment e (1988).

In sum, at the very least, under *Lohr* and *Bates*, Ms. Riegel is entitled to try her case under jury instructions that track applicable federal requirements.

## IV. The Background, Structure, and Purpose of the MDA Demonstrate That Section 360k(a) Does Not Broadly Preempt Damages Claims.

**A.** Medtronic does not contest that, in enacting the MDA, Congress did not express a word of concern about damages claims. It does not contest that Congress's enactment of § 360k(a) was motivated by concern about California's medical device regulation, not concern about ongoing products liability

litigation against device manufacturers. And although the FDA designated certain devices as PMA devices very soon after enactment of the MDA, Medtronic does not contest that device manufacturers did not conceive the notion that § 360k(a) might preempt damages claims until nearly 15 years later.[5]

Nonetheless, Medtronic argues that the plain language of § 360k(a) compels a finding of preemption. It begins (at 26-27) by stating that *Lohr*'s "holding" is that state-law damages claims constitute requirements under § 360k(a). That statement is incorrect. Although five members of the Court expressed the view that tort duties can constitute "requirements" under § 360k(a), the point was neither part of the Court's holding nor necessary to it. And while Medtronic is correct that *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992), and *Bates*, 544 U.S. at 443, hold that common-law rules can constitute "requirements" within the meaning of the Public Health Cigarette Smoking Act of 1969 ("Cigarette Labeling Act") and the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), the Court has also recognized that the word does not "invariably carry this meaning." *Bates*, 544 U.S. at 443; *see also Sprietsma*, 537 U.S. at 63 (statute that preempts "a law . . . imposing a requirement" does not preempt common law).

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[5]Medtronic states that the preemption argument was not made with respect to PMA devices for so many years because the FDA did not approve PMA devices for some time after 1976. In reality, a few devices were deemed to have PMA upon enactment of the MDA. 21 U.S.C. § 360(j)(l); *see, e.g.*, 21 C.F.R. § 886.3600 (intraocular lenses). The FDA otherwise issued its first PMA in April 1979. *See Michael v. Shiley, Inc.*, 46 F.3d 1316, 1320 (3d Cir. 1995). By the mid-1980s, injury caused by that device resulted in "numerous lawsuits." *Bowling*, 143 F.R.D. at 147; *see, e.g., Khan v. Shiley, Inc.*, 266 Cal. Rptr. 106, 108 (Cal. Ct. App. 1990) (complaint filed in 1986). Moreover, prior to *Lohr*, device manufacturers made little distinction between PMA and 510(k) for preemption purposes, yet Medtronic offers no reason for the long delay in making the preemption argument as to 510(k) devices.

Therefore, Medtronic cannot rely on those statutes to demonstrate Congress's intent in enacting § 360k(a) of the MDA.

Medtronic disagrees with Ms. Riegel's reading of § 360k(a), which is based on the rule of construction that a word is presumed to have the same meaning each time that it is used in a single statute or, as here, a single sentence. *See Commissioner v. Lundy*, 516 U.S. 235, 250 (1996). It argues (at 29) that § 360k(a) restricts the federal preemptive requirements to positive enactments through the phrase "applicable under this chapter to the device," but does not restrict preempted state requirements by repeating that phrase. Read in context, however, that argument falls apart. State requirements are limited to those "with respect to a device," just as federal requirements are limited to those "applicable under this chapter to a device." Because state requirements could come from a variety of sources—the statutes and regulations of various states—the exact wording used in regard to the federal requirements could not be applied to the state requirements. Nonetheless, taken as a whole, § 360k(a) evinces Congress's intent that preempted state requirements be "counterparts"—in the word of the relevant FDA regulation, 21 C.F.R. § 808.1(d), and *Lohr*, 518 U.S. at 500—to the federal requirements. Medtronic's reading also ignores the legislative history, which refers to preemption only of state statutes and regulations, and the regulatory commentary accompanying issuance of 21 C.F.R. § 808.1, which often mentions state positive law but never once mentions damages claims. *See* 43 Fed. Reg. 18661. Furthermore, even if Medtronic's reading were plausible, in light of the presumption against preemption, the Court has "a duty to accept the reading that disfavors preemption." *Bates*, 544 U.S. at 449.

Arguing that § 360k(a) should be read in context, Ms. Riegel's opening brief pointed to § 360k(b)—the provision that allows the FDA to exempt state requirements from preemption—in support of the argument that § 360k(a) does not

encompass damages claims. Medtronic responds that not every preempted requirement need be amenable to being exempt from preemption. However, in light of the strong presumption against preemption and Congress's striking silence with respect to preemption of damages claims, Medtronic's reading, while possible, is not the most plausible. Further, Medtronic offers no explanation why Congress would single out patients' only means of seeking compensation for injuries caused by defective devices by not allowing an exemption for damages claims, while allowing the possibility of exemption for other sorts of state laws, including laws that directly regulate devices. In contrast, the United States suggests (at 17) that the FDA may be able to exempt common-law duties that are sufficiently specific, but it offers no example applicable in a product liability case. In addition, like Medtronic, the United States has no answer to the practical impediments to seeking an exemption for a common-law duty, other than to say that not every "requirement" needs to fit within the framework of § 360k(b).

**B.** Medtronic suggests (at 32) that the Court not pay too much attention to the background and purpose of the MDA, and its brief generally follows its own advice. Instead, Medtronic focuses (at 32) on a single line in Ms. Riegel's opening brief, which states that "[i]n 1976, for Congress to have preempted damages claims without providing an alternative means of compensation would have been unprecedented." Pet. Br. 18. By 1976, Medtronic says, Congress had already preempted damages claims against cigarette companies through the Cigarette Labeling Act. That statute does not contradict Ms. Riegel's point, however, because preemption under the Cigarette Labeling Act applies only to certain failure-to-warn claims, and not to design, fraud, or other claims. *Cipollone*, 505 U.S. at 530-31.[6]

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[6]Medtronic also cites ERISA to show that Congress has sometimes preempted state-law claims, but ERISA provides an alternative

(continued...)

In contrast, below, Medtronic argued that *all* claims against it are preempted. *See* 2d Cir. App. A-3 (answer), A-28, A-34-A-36 (motion for summary judgment and affidavit in support thereof). This broad argument was typical of the preemption arguments made by PMA device manufacturers, who often seek preemption as to every claim alleged. *See, e.g., Horn v. Thoratec Corp.*, 376 F.3d 163, 165 (3d Cir. 2004); *Kemp v. Medtronic, Inc.*, 231 F.3d 216, 219 (6th Cir. 2000). Now, Medtronic attempts to minimize the breadth of its position by suggesting (at 33) that the scope of preemption is "exceedingly small" because patients injured by PMA devices may still bring claims for failure to comply with FDA-approved design, manufacturing, and labeling specifications. However, the vast majority of injuries to patients caused by PMA devices are not from manufacturers' failure to market the device according to the specifications in the approved PMA, but from defects or inadequacies in those specifications that have either not been identified or not been addressed in time to prevent injury. *See, e.g., In re Medtronic*, 465 F. Supp. 2d 886; *In re Guidant Corp.*, 2007 WL 1725289 (June 12, 2007); *Horn*, 376 F.3d 163; *Kemp*, 231 F.3d 216; *Bowling*, 143 F.R.D. 141.

Similarly, Medtronic (at 49) tries to avoid the consequences of its position by downplaying the number of PMA devices and the injuries they cause. First, Medtronic ignores Congress's intent, firmly established in the MDA, that the FDA require PMA for *all* class III devices. 21 U.S.C. §§ 360e(b)(1), 360e(i); *see* Pet. Br. 4. Second, Medtronic vastly understates

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[6](...continued)
remedy scheme. *See* 29 U.S.C. § 1132(a)(1)(B). Responding to the same sentence of the opening brief, amicus Chamber of Commerce (at 15) cites FIFRA and the Federal Railroad Safety Act ("FRSA"). As with the Cigarette Labeling Act, FIFRA preempts some labeling claims, but not other claims. *See Bates*, 544 U.S. at 444, 447. FRSA allows the Secretary of Transportation to preempt common-law duties in some circumstances but does not itself preempt any. 45 U.S.C. § 434 (1970), *recodified as amended at* 49 U.S.C. § 20106.

the percentage of class III devices that reach the market through PMA by comparing PMA submissions in 2005 to *all* 510(k) submissions that year, not only those submitted for class III devices and not only those submitted for new products. In fact, after excluding class I and II devices, the FDA's databases show that, in fiscal year 2005, 42.5 percent of class III submissions seeking permission to market new devices were PMA applications. If submissions regarding modifications to existing devices are included, more than 92 percent of class III submissions that year were for PMA devices.[7] Third, PMA devices cause a great number of serious injuries. *See* Pet. Br. 44-46 (citing examples); AARP Br. 20-26, 28-30 (same). The ramifications of barring patients from seeking compensation for these injuries are very significant. The notion that Congress did so without a word of debate is not credible.

## CONCLUSION

The decision below should be reversed and the case remanded for a trial on the merits.

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[7]These figures were calculated using the FDA databases available at www.fda.gov/cdrh/pmapage.html#pma (pma.zip) and www.fda.gov/cdrh/510khome.html, 1996-current (PMN96CUR.ZIP), merging them with the FDA device classification database, available at www.fda.gov/cdrh/prdcddes.html, and sorting by date of submission and class of device.

Medtronic also suggests (at 50) that if manufacturers remain liable for injuries caused by PMA devices, they will file 510(k) submissions, rather than PMA applications. There is no evidence to support the notion that manufacturers ever seek PMA when the FDA would allow them to market their products through 510(k).

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No. 06-179

IN THE
# Supreme Court of the United States

CHARLES R. RIEGEL and DONNA S. RIEGEL,
*Petitioners,*

v.

MEDTRONIC, INC.,
*Respondent.*

On Petition for a Writ of Certiorari to the
United States Court of Appeals for the Second Circuit

## SUPPLEMENTAL BRIEF FOR PETITIONERS

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## TABLE OF AUTHORITIES

CASES Pages

*Bates v. Dow AgroSciences*,
544 U.S. 431 (2005) ..... 1, 3, 4

*Christensen v. Harris*,
529 U.S. 576 (2000) ..... 6

*Cipollone v. Liggett Group*,
505 U.S. 504 (1992) ..... 1, 3, 5

*Geier v. American Honda Motor Co.*,
529 U.S. 861 (2000) ..... 1

*Goodlin v. Medtronic*,
167 F.3d 1367 (11th Cir. 1999) ..... 1

*Horn v. Thoratec*,
376 F.3d 163 (3d Cir. 2004) ..... 4

*Kernats v. Smith Industries Medical Systems*,
669 N.E.2d 1300 (Ill. App. Ct.),
*appeal denied*, 675 N.E.2d 634 (Ill. 1996),
*cert. denied*, 522 U.S. 1044 (1998) ..... 2

*Maislin Industries v. Primary Steel, Inc.*,
497 U.S. 116 (1990) ..... 6

*Mears v. Marshall*,
944 P.2d 984 (Or. Ct. App. 1997),
*review denied*, 961 P.2d 217 (Or. 1998) ..... 2

*Medtronic, Inc. v. Lohr*,
518 U.S. 470 (1996) ..... 1, 3, 4, 5, 6

*Niehoff v. Surgidev*,
950 S.W.2d 816 (Ky. 1997) ..... 3

*Norfolk Southern Railway Co. v. Shanklin*,
529 U.S. 344 (2000) ..... 4

*Oja v. Howmedica*,
111 F.3d 782 (10th Cir. 1997) ..... 3

*Sprietsma v. Mercury Marine*,
537 U.S. 51 (2002) ..... 1

*United States v. Mead Corp.*,
533 U.S. 218 (2001) ..... 6

*Weiland v. Telectronics Pacing Systems*,
721 N.E.2d 1149 (Ill. 1999) ..... 1

*Wutzke v. Schwagler*,
940 P.2d 1386 (Wash. Ct. App. 1997),
*review denied*, 953 P.2d 96 (Wash. 1998) ..... 2

STATUTES AND REGULATIONS

21 U.S.C. § 360k(a) ..... 4, 5

21 C.F.R. § 808.1 ..... 4, 5, 6

21 C.F.R. § 814.39(d)(2) ..... 6

21 C.F.R. § 861.1(b) ..... 5

Petitioners Charles and Donna Riegel file this supplemental brief in response to the amicus curiae brief of the United States on May 23, 2007.

In 1997, the government told the Court that the question whether section 360k(a) of the Medical Device Amendments ("MDA") expressly preempts state-law claims seeking damages for injuries caused by medical devices "involves an issue of substantial importance that has divided the lower courts" and that "[t]he current division among the lower courts on that issue would normally provide a strong justification" for the Court's review. Br. for the U.S. as Amicus Curiae in *Smith Indus. Med. Sys. v. Kernats*, No. 96-1405, at 9, 18 (Dec. 2007) ("U.S. Br. in *Kernats*"). Today, indisputably, the division among the lower courts remains. Indeed, the two principal cases on the no-preemption side of the conflict post-date the filing of the Solicitor General's brief in *Kernats*. *See Goodlin v. Medtronic*, 167 F.3d 1367 (11th Cir. 1999); *Weiland v. Telectronics Pacing Sys.*, 721 N.E.2d 1149 (Ill. 1999). What has changed since 1997 is the government's view on the merits of the question presented. The government's inconsistency on this question of statutory meaning only underscores the need for this Court to resolve the question presented.

1. The government agrees that the lower courts are divided over the answer to the question presented. Like petitioner Medtronic, the government (at 18) asks the Court not to bother with the conflict because there are more courts on one side of it than on the other. If this circumstance warranted denial of petitions for certiorari, then this Court would never have granted the petitions in *Bates v. Dow AgroSciences*, 544 U.S. 431 (2005); *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002); *Geier v. American Honda Motor Co.*, 529 U.S. 861, 867-68 (2000); *Medtronic v. Lohr*, 518 U.S. 470 (1996), or *Cipollone v. Liggett Group*, 505 U.S. 504 (1992)—all of which resolved lopsided splits concerning express preemption of tort

claims by rejecting the holdings of a majority of the lower courts.

Also like Medtronic, the government (at 19) asks the Court to overlook the undisputed conflict because it might simply go away. As discussed in Petitioners' Reply (at 1-2), this speculation is unfounded. Nonetheless, referring to *Goodlin* and *Weiland*, the government (at 20) repeats Medtronic's suggestion that the Eleventh Circuit and the Illinois Supreme Court are likely to overrule their own holdings that section 360k(a) does not expressly preempt damages claims involving premarket approval ("PMA") devices merely because they are in the minority. Yet those courts have long been in the minority; and, after more than eight years, neither has intimated that it is dissatisfied with its minority view.[1]

The government (at 18-19 n.5) also tries to distinguish the cases holding that state-law damages claims are not sufficiently specific to prompt preemption under section 360k(a), but neither of its distinctions survives scrutiny. First, the government points out, as did Medtronic, that some of those cases did not involve PMA devices. To begin with, some of those cases *did* involve PMA devices. *See, e.g., Mears v. Marshall*, 944 P.2d 984 (Or. Ct. App. 1997), *review denied*, 961 P.2d 217 (Or. 1998); *Wutzke v. Schwagler*, 940 P.2d 1386 (Wash. Ct. App. 1997), *review denied*, 953 P.2d 96 (Wash. 1998); *Kernats v. Smith Indus. Med. Sys.*, 669 N.E.2d 1300 (Ill. App. Ct.), *appeal denied*, 675 N.E.2d 634 (Ill. 1996), *cert. denied*, 522 U.S. 1044 (1998). In any event, the government's

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[1] In this regard, the government fails to acknowledge the federal district court and state appellate court decisions that, like the Eleventh Circuit and the Illinois Supreme Court, have held that PMA is not a preemptive requirement under section 360k(a). *See* Pet. 15-16 (citing cases).

distinction is irrelevant because consideration of the state-law side of the preemption analysis does not turn on the type of device at issue, but rather on the fact that the state-law "requirements" at issue are too general to give rise to preemption under *Lohr*. *See* 518 U.S. at 500. These decisions squarely conflict with the decisions of courts that have held that section 360k(a) does preempt state laws of general applicability. *See* Pet. 17-18 (citing cases); Pet. Reply 9-10 (responding to same point).

Second, the government (at 19 n.5) says that both *Oja v. Howmedica*, 111 F.3d 782 (10th Cir. 1997), and *Niehoff v. Surgidev*, 950 S.W.2d 816 (Ky. 1997), held that a finding of liability under state law would not impose a "requirement" and that this "premise" was rejected in *Bates*. *See* 544 U.S. at 443. To begin with, the point that state tort law can impose "requirements" did not originate with *Bates*, but more than 20 years earlier, *see Cipollone*, 505 U.S. at 521-22, and was recognized in *Lohr* itself. *See* 518 U.S. at 488 (plurality); *id.* at 500 (majority). More importantly, neither *Oja* nor *Niehoff* held that state-law liability *cannot* impose a requirement. Rather, those cases held that each state-law claim at issue did not "constitute a state requirement developed *'with respect to' a medical device*," as required by section 360k(a) and *Lohr*. *Oja*, 111 F.3d at 789 (quoting *Lohr*) (emphasis added); *see Niehoff*, 950 S.W.2d at 822 (state laws of general applicability not preempted under 21 C.F.R. § 808.1(d) and *Lohr*).

2. The Solicitor General's suggestion (at 19) that the government's about-face on the merits—first espousing a narrow reading of the MDA's express preemption provision and later a very broad one—will lead courts that have held that premarket approval is not preemptive to reconsider their holdings is unsupported by a single example and belied by the history of litigation in this area. Thus, although the government's own reversal is now more than three years old, no court

has reversed its prior position. Moreover, judges have dissented from the decisions of each of the two federal circuit courts to have addressed the issue since the government's new-found views were announced. *See* Pet. App. 43a (Pooler, J., dissenting); *Horn v. Thoratec*, 376 F.3d 163, 180 (3d Cir. 2004) (Fuentes, J., dissenting).

In addition, from 1996 (when the government filed its brief in *Lohr*), to 1997 (when it filed its brief in *Kernats*), through 2003, the government's view was that section 360k(a) does not generally preempt damages claims associated with PMA devices. Many courts nonetheless held the opposite. There is no reason to think that the government's decision to reverse itself will lead courts also to reverse themselves.

For two reasons, speculation that courts will alter their views in reaction to the government's about-face is particularly improbable here. First, in two recent cases, this Court refused to defer to the government's construction of an express preemption provision when the government's view had been inconsistent. *See Bates*, 544 U.S. at 449; *Norfolk S. Ry. Co. v. Shanklin*, 529 U.S. 344, 356 (2000). Those cases make clear that statutory language, not the government's position *du jour*, is the primary basis for construing an express preemption provision. Second, the most relevant government viewpoint for purposes of construing the MDA's preemption provision, 21 U.S.C. § 360k(a), is not the one adopted in the government's most recent amicus brief, but the one adopted by the Food and Drug Administration ("FDA") in a regulation promulgated through notice-and-comment rulemaking. Accordingly, in *Lohr*, the Court did not give weight to the Solicitor General's amicus brief, but to 21 C.F.R. § 808.1, a regulation issued by the FDA in connection with its authority to exempt state requirements from preemption. *See Lohr*, 518 U.S. at 495-97. That regulation remains in effect and does not support the position taken by the government on the merits. *See id.*; Pet. 8,

20. Remarkably, the government's brief does not even cite section 808.1.

3. The great majority of the government's brief is devoted to arguing the *merits* of the question whether premarket approval of a medical device preempts state-law damages claims for personal injury caused by that device. In doing so, the government skims past the statutory language and makes no effort to reconcile its position with congressional intent, the "ultimate touchstone" of express preemption analysis. *Lohr*, 518 U.S. at 485; *Cipollone*, 505 U.S. at 516.

The Riegels strongly disagree with the government's argument. As construed in *Lohr*, section 360k(a) requires a comparison of a device-specific federal requirement with a state counterpart requirement "with respect to" medical devices. 518 U.S. at 500-01 (majority opinion). The government's argument, however, does not even attempt to operate within this rubric. And it ignores the distinction, described in its *Kernats* brief, between the general requirements of PMA and performance standards that impose specific requirements on particular devices. *See* 21 C.F.R. § 861.1(b); U.S. Br. in *Kernats* at 15 (making this distinction); *see also* Pet. 8 (examples of device-specific federal requirements); *Lohr*, 518 U.S. at 504 (Breyer, J., concurring) (example of device-specific state requirement).

Although this supplemental cert.-stage brief is not the place for a full discussion of the merits, two additional points are worth mentioning. First, the government (at 11) states that, after Medtronic's device was approved, the company "could not lawfully implement any changes that would affect safety or efficacy of the device without submitting a supplemental application to the FDA (and, in most instances, receiving prior approval)." Here, there is no evidence that Medtronic ever sought FDA approval to make changes to address the defects alleged by the Riegels. Thus, any regulatory requirement that

the FDA approve such changes is beside the point. More fundamentally, the deficiency in the label of Medtronic's device could have been corrected without prior FDA approval, pursuant to 21 C.F.R. § 814.39(d)(2) (company may make labeling changes, prior to FDA approval, to "add or strengthen a contraindication, warning, [or] precaution," or to "add or strengthen an instruction that is intended to enhance the safe use of the device"). Medtronic never attempted to do so.

Although generally trying to distance this case from *Lohr*, the government (at 10) tries to use *Lohr* in support of a call for deference to the government's view. In *Lohr*, however, as noted above, the Court did not defer to the government's brief, but to an FDA regulation, 21 C.F.R. § 808.1, issued in 1979. Read in the context of the paragraph of the *Lohr* majority opinion from which they were pulled, the sentences quoted in the government's brief unambiguously address the weight to be accorded to that regulation. *See Lohr*, 518 U.S. at 496-97. Post-*Lohr* opinions explaining that the degree of weight accorded to an agency's views depends on, among other things, the consistency and formality of those views, further counsel against according substantial weight to the view of the merits stated in the government's brief, as opposed to the agency's longstanding regulation. *See United States v. Mead Corp.*, 533 U.S. 218, 228 (2001); *Christensen v. Harris*, 529 U.S. 576, 587 (2000); *cf. Maislin Indus. v. Primary Steel, Inc.*, 497 U.S. 116, 131 (1990) ("Once we have determined a statute's clear meaning, we adhere to that determination under the doctrine of *stare decisis*, and we judge an agency's later interpretation of the statute against our prior determination of the statute's meaning.").

4. The government (at 16-17) implies that its argument against preemption in *Smith Medical Systems Industries v. Kernats* was based on a proposed FDA interpretive rule that was about to be issued. The *Kernats* brief belies that implica-

tion. There, the government argued for four pages that PMA and IDE ("investigational device exemption") "do not displace state law standards of care or common law duties respecting the medical device" because they are not "device specific" requirements within the meaning of section 360k(a). U.S. Br. in *Kernats* at 15; *see id.* at 14-18. Those pages do not mention the proposed rule. Then, the government turned to the proposed interpretive rule and argued that the rule provided an independent reason for the Court to "defer review," not because the proposed rule affected the Solicitor General's view on the merits, but because the rule might affect the lower courts' views. *Id.* at 18.

In *Kernats*, aside from its view that the Court's review was not warranted because the holding that PMA does not preempt damages claims was correct, the government argued that because the decision below was not a final judgment under 28 U.S.C. § 1257, and because a new interpretive rule might influence the lower courts' views on the question presented, the Court should not grant that petition. Here, the Court has jurisdiction under 28 U.S.C. § 1254, and no relevant proposed rule is pending. Accordingly, the reasons argued by the Solicitor General for denying the petition in *Kernats* are not present. Here—almost ten years after the Solicitor General first noted the "division among the lower courts" that "would normally provide a strong justification for this Court to grant review and definitively resolve the conflict"—there is no jurisdictional hurdle, no pending rule, and no impediment to this Court's resolution of the longstanding conflict.

## CONCLUSION

The petition for a writ of certiorari should be granted.

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No. 06-179

# In the Supreme Court of the United States

DONNA S. RIEGEL, INDIVIDUALLY AND AS ADMINISTRATOR OF THE ESTATE OF CHARLES R. RIEGEL, PETITIONER

*v.*

MEDTRONIC, INC.

*ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT*

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## QUESTION PRESENTED

Whether, under the express preemption provision in 21 U.S.C. 360k, the Food and Drug Administration's premarket approval of a medical device preempts state-law tort claims relating to the safety or efficacy of that device.

## TABLE OF CONTENTS


Page

Interest of the United States ..... 1
Statement ..... 1
Summary of argument ..... 6
Argument:
FDA's premarket approval of a medical device preempts state tort claims challenging the design or labeling approved by FDA ..... 8
A. FDA's premarket approval process imposes specific federal requirements ..... 8
B. Petitioners' tort claims would impose state-law requirements ..... 15
C. The state-law requirements at issue here are different from, or in addition to, the federal requirements ..... 19
1. Common-law claims are preempted insofar as they assert that a device in its FDA-approved form is not safe or effective for use as directed in the FDA-approved labeling ..... 19
2. The claims at issue here would interfere with FDA's expert balancing of health risks and benefits ..... 20
3. The federal and state requirements at issue here are not equivalent ..... 24
D. Preemption does not turn on whether state requirements also apply to matters other than medical devices intended for human use ..... 26
E. The presumption against preemption does not control this case ..... 30
Conclusion ..... 30

## TABLE OF AUTHORITIES

Cases: Page

*Adickes* v. *S.H. Kress & Co.*, 398 U.S. 144 (1970) ..... 25
*Auer* v. *Robbins*, 519 U.S. 452 (1997) ..... 24, 28
*Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431 (2005) ..... 16, 17, 25, 26
*Brooks* v. *Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001), cert. denied, 535 U.S. 1056 (2002) ..... 13
*Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001) ..... 9
*Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311 (1981) ..... 23
*Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992) ..... 16, 17
*FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120 (2000) ..... 11
*Geier* v. *American Honda Motor Co.*, 529 U.S. 861 (2000) ..... 23
*Hines* v. *Davidowitz*, 312 U.S. 52 (1941) ..... 24
*Ling* v. *Liquors*, 703 P.2d 731 (Kan. 1985) ..... 18
*Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996) ..... *passim*
*Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374 (1992) ..... 27
*Motor Vehicle Mfrs. Ass'n* v. *State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29 (1983) ..... 24
*San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236 (1959) ..... 16
*United States* v. *Rutherford*, 442 U.S. 544 (1979) ..... 11

Statutes and regulations: Page

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. 301 *et seq.* ..... 1
21 U.S.C. 355(d) ..... 11
Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. 136v(b) ..... 25
Medical Device Amendments of 1976, 21 U.S.C. 360c *et seq.* ..... 1
21 U.S.C. 360c(a)(1) ..... 2
21 U.S.C. 360c(a)(1)(A) ..... 2
21 U.S.C. 360c(a)(1)(B) ..... 2
21 U.S.C. 360c(a)(1)(C) ..... 2
21 U.S.C. 360c(a)(2)(C) ..... 3, 11
21 U.S.C. 360e(a) ..... 2
21 U.S.C. 360e(b)(1)(A) ..... 2
21 U.S.C. 360e(b)(1)(B) ..... 2
21 U.S.C. 360e(c)(1) ..... 2, 9
21 U.S.C. 360e(c)(2) ..... 10
21 U.S.C. 360e(d) ..... 11
21 U.S.C. 360e(d)(1)(A) ..... 3, 9
21 U.S.C. 360e(d)(1)(B) ..... 3
21 U.S.C. 360e(d)(1)(B)(ii) ..... 3
21 U.S.C. 360e(d)(2) ..... 10
21 U.S.C. 360e(d)(2)(A) ..... 3, 9
21 U.S.C. 360e(d)(2)(B) ..... 3, 9
21 U.S.C. 360e(d)(2)(D) ..... 3, 9
21 U.S.C. 360e(d)(3)(A)(ii) ..... 10
21 U.S.C. 360e(d)(6) ..... 13
21 U.S.C. 360e(d)(6)(A)(i) ..... 3

Statutes and regulations—Continued: Page

21 U.S.C. 360e(d)(6)(B) ..... 3
21 U.S.C. 360e(e)(1) ..... 4, 22
21 U.S.C. 360h(d) ..... 18
21 U.S.C. 360i(a) ..... 3
21 U.S.C. 360j(e)(1) ..... 3
21 U.S.C. 360k ..... *passim*
21 U.S.C. 360(k) ..... 2, 8
21 U.S.C. 360k(a) ..... 4, 5, 7, 8, 19, 26
21 U.S.C. 360k(b) ..... 4, 17
21 U.S.C. 360k(b)(1) ..... 18
N.Y. Gen. Oblige. Law § 11-101 (McKinney 2001) ..... 18
21 C.F.R. (2006):
Pt. 803 ..... 3
Section 803.10(c)(1) ..... 3
Section 803.10(c)(2)(i) ..... 4
Section 803.50(a)(1)-(2) ..... 3
Section 803.55(b) ..... 4
Pt. 808:
Section 808.1(b) ..... 5, 27, 28
Section 808.1(d) ..... 4, 15
Section 808.1(d) (1995) ..... 9, 11
Section 808.1(d)(1) ..... 27
Section 808.1(d)(2) ..... 20
Section 808.1(d)(6)(ii) ..... 5, 28
Section 808.20(c)(1) ..... 18

Regulations—Continued: Page

Pt. 814:
Section 814.20 ..... 2, 9
Section 814.20(b)(13) ..... 2
Section 814.37(b) ..... 10
Section 814.39(a) ..... 3, 13
Section 814.39(c) ..... 3, 13
Section 814.39(d) ..... 3, 14
Section 814.44 ..... 2
Section 814.44(a) ..... 10
Section 814.44(b) ..... 10
Section 814.44(e) ..... 10, 14
Section 814.44(f) ..... 10, 15
Section 814.45 ..... 10
Section 814.82(a)(1) ..... 3
Section 814.84 ..... 4
Section 814.84(b)(2) ..... 4

Miscellaneous:

Cathy L. Backinger & Patricia A. Kingsley, FDA, *Write It Right* (1993) ..... 13

*FDA's Role in Protecting and Promoting Public Health: Testimony Before the Senate Comm. on Labor and Human Resources*, 104th Cong., 2d Sess. (1996) <http://www.hhs.gov/asl/testify/t960221a.html> ..... 12

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*Alert for Healthcare Professionals* (2005) <http://www.fda.gov/cder/drug/InfoSheets/HCP/valdecoxibHCP.pdf> ..... 12

Miscellaneous—Continued: Page

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*Memorandum* (2005) <http://www.fda.gov/cder/drug/infopage/COX2/NSAIDdecisionMemo.pdf> .... 12

*Summary of Safety and Probable Benefit* (2004) <http://www.fda.gov/cdrh/pdf3/H030003b.pdf> ..... 12

42 Fed. Reg. 30,384 (1977) ..... 27

44 Fed. Reg. 37,447 (1979) ..... 13

61 Fed. Reg. 44,413 (1996) ..... 11, 19

65 Fed. Reg. 81,083 (2000) ..... 11

71 Fed. Reg. 3935 (2006) ..... 13, 22

H.R. Rep. No. 853, 94th Cong., 2d Sess. (1976) ... 12, 13, 22

S. Rep. No. 33, 94th Cong., 1st Sess. (1975) ..... 19

# In the Supreme Court of the United States

No. 06-179

DONNA S. RIEGEL, INDIVIDUALLY AND AS ADMINISTRATOR OF THE ESTATE OF CHARLES R. RIEGEL, PETITIONER

*v.*

MEDTRONIC, INC.

*ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT*

## BRIEF FOR THE UNITED STATES AS AMICUS CURIAE SUPPORTING RESPONDENT

### INTEREST OF THE UNITED STATES

This case presents the question whether the Food and Drug Administration's (FDA's) premarket approval of a medical device preempts state claims relating to the safety or efficacy of that device. FDA administers the premarket approval process for medical devices and monitors devices' safety after they are marketed. The decision in this case will affect that responsibility. At the Court's invitation, the United States filed a brief as amicus curiae at the petition stage of this case.

### STATEMENT

1. a. The Medical Device Amendments of 1976 (MDA), 21 U.S.C. 360c *et seq.*, to the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 301 *et seq.*, sort medical devices into three classes. See 21 U.S.C. 360c(a)(1). Class I and II devices are subject to regulatory controls or standards, but do not require pre-

market approval. See 21 U.S.C. 360c(a)(1)(A) and (B); *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 476-477 (1996).

A device falls within Class III if (i) it "presents a potential unreasonable risk of illness or injury," or is purported to be used to sustain or support human life or to have substantial importance in preventing impairment of human health, and (ii) there is inadequate evidence for FDA to determine that controls or standards authorized for Class I or II devices would provide reasonable assurance of safety and effectiveness. 21 U.S.C. 360c(a)(1)(C). In general, a Class III device requires premarket approval (PMA) by FDA unless it was marketed for use before the MDA's enactment or it is "substantially equivalent" to a device that is already lawfully on the market. 21 U.S.C. 360e(a) and (b)(1)(A) and (B), 360(k). Fewer than 1% of new devices require premarket approval. Pet. App. 13a.

FDA's PMA process for the relatively few devices that require it is "rigorous." *Lohr*, 518 U.S. at 477. A manufacturer must submit: full reports of all studies and investigations, including clinical investigations, of the device's safety and effectiveness; a full statement of the components, ingredients, properties, and principles of operation of the device; a full description of the methods used in, and facilities and controls used for, the manufacture, processing, packing, and installation of the device; a reference to any performance standard that would apply if the device were a Class II device, and information showing that the device satisfies that standard or justifying any deviation from it; any sample of the device or its components requested by FDA; and the proposed labeling. See 21 U.S.C. 360e(c)(1); 21 C.F.R. 814.20. FDA may request additional information from the manufacturer, and may also consult with a scientific advisory committee made up of outside experts. See 21 C.F.R. 814.44, 814.20(b)(13). The agency conducts an in-depth review of requests for premarket approval, devoting an average of 1,200 hours to each application. See *Lohr*, 518 U.S. at 477.

FDA may grant premarket approval for a Class III device only if it finds, among other things, that (i) there is "reasonable assurance" of the device's "safety and effectiveness" under the conditions of use included in the proposed labeling, and (ii) the proposed labeling is neither false nor misleading. 21 U.S.C. 360e(d)(1)(A), (2)(A), (B) and (D). In determining safety and effectiveness, FDA must "weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." 21 U.S.C. 360c(a)(2)(C). FDA may impose restrictions on the sale or distribution of the device as a condition of premarket approval, see 21 U.S.C. 360e(d)(1)(B)(ii); 21 C.F.R. 814.82(a)(1), and it may also impose device-specific restrictions by regulation, see 21 U.S.C. 360j(e)(1).

Following FDA's premarket approval, a manufacturer must submit a supplemental application to FDA and receive its approval before making any changes to a device that affect its safety or effectiveness. See 21 U.S.C. 360e(d)(6)(A)(i); 21 C.F.R. 814.39(a). The same process that applies to an original PMA application generally applies to a supplemental application. See 21 U.S.C. 360e(d)(6)(B); 21 C.F.R. 814.39(c). With only narrow exceptions, the manufacturer also must receive FDA's approval before making any changes to the labeling of a device. See 21 C.F.R. 814.39(a) and (d)(1).

Manufacturers are also required to collect and report to FDA information on certain adverse events related to the device after it has been approved. See 21 U.S.C. 360i(a); 21 C.F.R. Pt. 803. The manufacturer must report within 30 days any incident in which a device may have caused or contributed to a death or serious injury, or in which the device malfunctioned in a manner that would likely cause or contribute to serious injury if the malfunction recurred. See 21 C.F.R. 803.10(c)(1), 803.50(a)(1)-(2). The manufacturer must report such an incident within five days if remedial action is required "to prevent an unreasonable

risk of substantial harm to the public health." See 21 C.F.R. 803.10(c)(2)(i).

A device manufacturer is also required to provide annual reports to FDA. See 21 C.F.R. 803.55(b), 814.84. Among other things, an annual report must identify any reports in the scientific literature about the device, as well as any unpublished reports of data from clinical investigations or nonclinical laboratory studies involving the device about which the manufacturer knows or reasonably should know. See 21 C.F.R. 814.84(b)(2).

Based on new information reported to FDA or other information known to the agency, FDA may withdraw premarket approval of a Class III medical device if it finds, among other things, that the device no longer satisfies the standards for premarket approval. 21 U.S.C. 360e(e)(1).

b. The MDA's express preemption provision states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter.

21 U.S.C. 360k(a). FDA is authorized to exempt some state or local requirements from preemption. 21 U.S.C. 360k(b).

FDA's regulations implementing Section 360k provide that "State or local requirements are preempted only when [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device." 21 C.F.R. 808.1(d). The regulations further explain that state or local requirements potentially subject to preemption include those "having the force and effect of law (whether established by

statute, ordinance, regulation, or court decision)." 21 C.F.R. 808.1(b). Under the regulations, a general state prohibition against adulterated or misbranded devices may be preempted if it "has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement," that "is different from, or in addition to, a Federal requirement." 21 C.F.R. 808.1(d)(6)(ii).

2. The Evergreen Balloon Catheter is a Class III medical device used to open clogged arteries. Pet. App. 3a. FDA granted premarket approval for the device in 1994, and approved respondent's supplemental applications in 1995 and 1996. *Id.* at 3a-4a. Charles Riegel was injured after an Evergreen Balloon Catheter ruptured while he was undergoing angioplasty. *Id.* at 4a. The physician used the device in contraindicated circumstances, and overinflated the device contrary to warnings on its label. *Ibid.*

Charles Riegel and his wife Donna Riegel brought this suit against respondent, alleging negligent design, testing, inspection, manufacture, distribution, labeling, marketing, and sale of the catheter; strict liability; breach of express warranty; breach of implied warranty; and loss of consortium. Pet. App. 4a-5a. The district court held that all of petitioners' claims except those for negligent manufacturing and breach of express warranty were preempted by Section 360k(a). See *id.* at 55a-74a. The court subsequently granted summary judgment to respondent on the merits of the non-preempted claims. *Id.* at 75a-91a.

3. The court of appeals affirmed. Pet. App. 1a-54a. In holding that the bulk of petitioners' claims were preempted, the court construed the term "requirement" in Section 360k to encompass the design and labeling for the device set forth in an approved PMA application. *Id.* at 26a-28a. The court explained that FDA may impose conditions on premarket approval in order to ensure that a device is safe and effective, and that federal law requires a manufacturer to comply with the specifications set forth in an approved PMA application. *Id.* at 9a.

The court of appeals determined that the imposition of tort liability based on the allegedly defective character of a device or label would subject the manufacturer to state-law requirements "different from, or in addition to," the federal requirements embodied in the approved PMA application. Pet. App. 32a, 35a-36a. In contrast, the court determined that petitioners' negligent manufacturing claim is not preempted because it is premised on an alleged violation of federal requirements. *Id.* at 36a.

While characterizing the question as a "close" one, Judge Pooler would have held that none of petitioners' claims are preempted. Pet. App. 43a, 50a-54a.

## SUMMARY OF ARGUMENT

The court of appeals correctly held that petitioners' claims are preempted to the extent that they seek to impose liability on respondent for not departing from an FDA-approved design or labeling requirement imposed in the premarket approval process. Section 360k generally preempts any state "requirement" that is "different from, or in addition to, any [federal] requirement" and that "relates to the safety or effectiveness of the device or to any other matter included in a [federal] requirement." 21 U.S.C. 360k(a).

For a Class III device to obtain premarket approval, FDA must determine that there is reasonable assurance that the device is safe and effective and that its label is not false or misleading. FDA undertakes an exhaustive scientific review to determine whether those requirements are satisfied. In doing so, FDA does not merely police minimum standards of safety. Instead, FDA weighs potential health risks against benefits. If the agency grants approval, it does so for a specific design and label based on that weighing, and the manufacturer is then barred from changing the FDA-approved design or label without FDA approval (subject only to limited exceptions that do not appear to apply here). Thus, the premarket approval process imposes federal requirements with preemptive effect under Section 360k.

The state-law claims in dispute here would impose requirements that are different from, or in addition to, those federal requirements. As five Justices concluded in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), state common-law damages actions impose "requirements" subject to preemption under Section 360k. The claims at issue here are premised on the assertion that the Evergreen Balloon Catheter, in the form and with the label approved by FDA, is not safe and effective. Thus, the common-law duties on which those claims are based would impose additional or different requirements. Moreover, subjecting a manufacturer to liability for not departing from an FDA-approved design or label would interfere with FDA's ability to protect public health by balancing the risks and benefits of a particular design or label. For example, a state requirement that additional warnings must be included in the labeling for a device could dilute the effectiveness of more meaningful risk information, or deter beneficial uses of the device, contrary to FDA's judgment that the existing label appropriately balances the health risks and benefits.

Finally, preemption is not limited to state requirements that apply *exclusively* to medical devices intended for human use, as petitioners contend. State requirements are preempted "with respect to a device intended for human use." 21 U.S.C. 360k(a). That means that Section 360k(a) does not preempt the application of general state requirements to matters *other than* devices intended for human use; it does not mean that States can regulate such devices in any way they wish so long as they also regulate other things as well.

## ARGUMENT

### FDA'S PREMARKET APPROVAL OF A MEDICAL DEVICE PREEMPTS STATE TORT CLAIMS CHALLENGING THE DESIGN OR LABELING APPROVED BY FDA

Congress expressly preempted, with respect to devices intended for human use, any state "requirement" that is "different from, or in addition to, any [federal] requirement" and that "relates to the safety or effectiveness of the device or to any other matter included in a [federal] requirement." 21 U.S.C. 360k(a). That provision precludes state tort suits to the extent that they seek to impose liability on a device manufacturer for *not* departing from an FDA-approved design or label.

#### A. FDA's Premarket Approval Process Imposes Specific Federal Requirements

The court of appeals correctly held that FDA's premarket approval of a Class III device imposes specific federal requirements applicable to the device, and thus has preemptive effect. Pet. App. 25a-29a.

1. *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), establishes the analytical framework for this case. In *Lohr*, this Court held that FDA's determination under 21 U.S.C. 360(k) that a device is substantially equivalent to a legally marketed device does not impose any federal "requirements" that preempt state law. See *Lohr*, 518 U.S. at 493. The Court explained that the manufacturer's contrary position in that case "exaggerate[d] the importance of the [substantial-equivalence] process," in part because FDA had determined only whether the device was substantially equivalent to a legally marketed device, not (as here) whether it was safe or effective. *Id.* at 492-493. In doing so, the Court emphasized that FDA's substantial-equivalence determination "is by no means comparable to the PMA process." *Id.* at 478-479.

This Court also held in *Lohr* that FDA's "general federal regulations governing the labeling and manufacture of all medi-

cal devices" do not preempt state tort claims. 518 U.S. at 497. The Court explained that, under FDA's regulations concerning the preemptive scope of the MDA, "state requirements are preempted 'only' when the FDA has established 'specific counterpart regulations or . . . other specific requirements applicable to a particular device.'" *Id.* at 498 (quoting 21 C.F.R. 808.1(d) (1995)). Those FDA preemption regulations are entitled to "substantial weight," in part because Congress delegated to FDA the authority to grant exemptions from preemption—an authority that requires FDA to assess the preemptive effect of the MDA and the agency's own actions on state laws. *Id.* at 496. Consistent with FDA's preemption regulations, the Court determined that the *general* federal mandates on which the manufacturer relied in *Lohr* "reflect[ed] important but entirely generic concerns about device regulation generally, not the sort of concerns regarding a specific device or field of device regulation" that give rise to preemption. *Id.* at 501.

2. As this Court recognized in *Lohr*, a premarket approval is "by no means comparable" to a substantial-equivalance determination under Section 360(k). 518 U.S. at 478-479; see *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001); Pet. App. 25a-27a. Unlike a substantial-equivalence determination, see *Lohr*, 518 U.S. at 493, FDA will grant premarket approval only if there is "reasonable assurance" that the device is safe and effective under the proposed conditions of use, and the proposed labeling is not "false or misleading in any particular," 21 U.S.C. 360e(d)(1)(A), (2)(A), (B) and (D). As part of FDA's "rigorous" review of those questions (*Lohr*, 518 U.S. at 477), an applicant is required to submit extensive information, including scientific studies that generally must be undertaken pursuant to FDA's published standards. See 21 U.S.C. 360e(c)(1); 21 C.F.R. 814.20; p. 2, *supra*.

FDA encourages applicants to meet with it before submitting an application, so that FDA can "provide the applicant with the

agency's determination of the type of valid scientific evidence that will be necessary." FDA, *Device Advice—Premarket Approval* (Device Advice) (visited Oct. 19, 2007) <http://www.fda.gov/cdrh/devadvice/pma/printer.html>. After an application is filed, FDA may request any additional information needed to determine whether the device is safe and effective and properly labeled. See 21 U.S.C. 360e(d)(3)(A)(ii); 21 C.F.R. 814.37(b). FDA may also refer an application to a panel of experts, who provide FDA with a "report and recommendation respecting approval of the application, together with all underlying data and the reasons or basis for the recommendation." 21 U.S.C. 360e(c)(2); see 21 C.F.R. 814.44(a) and (b). "In general, all PMAs for the first-of-a-kind device are taken before the appropriate advisory panel for review and recommendation." Device Advice.

If the available information is ultimately insufficient to provide reasonable assurance of safety or effectiveness, FDA does not approve the application. 21 U.S.C. 360e(d)(2). Instead, FDA will informally determine whether a manufacturer will voluntarily provide additional information or make changes to a device's design or label that would permit approval. If those discussions are unsuccessful, FDA will either: (i) issue an "approvable letter" stating that the agency could approve the application if the applicant submitted specific additional information or agreed to conditions on approval, 21 C.F.R. 814.44(e); (ii) issue a "not approvable letter" describing the deficiencies in the application, 21 C.F.R. 814.44(f); or (iii) deny the application outright, 21 C.F.R. 814.45. FDA approves about 60% of PMA applications. See FDA, *Annual Report* 41 (2004) <http://www.fda.gov/cdrh/annual/fy2004/ode/2004.pdf>. The other applicants typically receive approvable or not approvable letters. See *ibid.*

FDA devotes approximately 1,200 hours to a typical PMA review. See *Lohr*, 518 U.S. at 477. While this Court found that substantial-equivalance determinations "provide little protection to the public," *id.* at 493, premarket approvals reflect FDA's

expert judgment, rendered after exhaustive analysis, that there is reasonable assurance that the devices are in fact safe and effective and properly labeled.

3. FDA's premarket approval imposes "specific requirements applicable to a particular device." *Lohr*, 518 U.S. at 498 (quoting 21 C.F.R. 808.1(d) (1995)). The MDA requires that a device be safe and effective, and that its label not be false or misleading. 21 U.S.C. 360e(d). FDA's premarket approval gives specific content to those general requirements as applied to a particular device. The agency approves a specific design and label based on the agency's expert balancing of the health risks and benefits, and the MDA generally requires the manufacturer not to make subsequent changes without FDA's approval.

a. Contrary to petitioners' contention (Br. 24) that FDA reviews devices only for "minimum standards" of safety and effectiveness, the MDA directs FDA to "weigh[] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use," 21 U.S.C. 360c(a)(2)(C). Under that standard, FDA conducts a risk-benefit analysis to determine whether safety risks (whatever their magnitude) are warranted in light of the potential benefits. See, *e.g.*, H.R. Rep. No. 853, 94th Cong., 2d Sess. 16-17 (1976); Device Advice. FDA's risk-benefit balancing for devices is parallel to the risk-benefit balancing it undertakes pursuant to 21 U.S.C. 355(d) as part of the pre-market approval process for drugs. See *United States* v. *Rutherford*, 442 U.S. 544, 555 (1979) ("[T]he Commissioner generally considers a drug safe when the expected therapeutic gain justifies the risk entailed by its use.").

Applying that approach, FDA has, for example, approved cancer treatments that are highly toxic and thus not "safe" as that term is ordinarily used, but that are nonetheless safe in the relevant sense under the FDCA because the potential benefits to health outweigh the risks. 61 Fed. Reg. 44,413 (1996); see *FDA* v. *Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 142 (2000).

FDA has likewise approved a ventricular assist device for use in children with failing hearts, even though the survival rate for children with the device is under 50%. The agency explained that the device's benefits outweighed its significant risks. FDA, *Summary of Safety and Probable Benefit* 20 (2004) (Summary) <http://www.fda.gov/cdrh/pdf3/H030003b.pdf>.

In determining whether benefits outweigh risks, FDA may also consider the availability of other drugs, devices, or courses of treatment, as well as their safety profiles. As then-FDA Commissioner David Kessler testified in 1996, FDA "must determine if each new drug or device is safe enough in view of its anticipated benefits and the comparative benefit of other available treatments." *Testimony Before the Senate Comm. on Labor and Human Resources* <http://www.hhs.gov/asl/testify/t960221a.html>. Thus, when FDA approved the ventricular assist device discussed above, it relied in part on "the risks and benefits associated with alternative methods of treatment," which had high mortality rates. See Summary 20.

If similar, safer products are on the market, the agency requires a heightened health benefit to justify the heightened risk. For example, FDA determined in 2005 that Bextra should be withdrawn from the market because it presented greater safety risks than other drugs with comparable efficacy, and the manufacturer withdrew it. See FDA, *Alert for Healthcare Professionals* (2005) <http://www.fda.gov/cder/drug/InfoSheets/HCP/valdecoxibHCP.pdf>; *FDA Memorandum* 17 (2005) <http://www.fda.gov/cder/drug/infopage/COX2/NSAIDdecisionMemo.pdf>.

FDA also weighs the overall health consequences of including particular warnings in the labeling. As FDA has explained, "[e]xaggeration of risk could discourage appropriate use of a beneficial drug." 71 Fed. Reg. 3935 (2006). The same is true for devices. Excessive warnings in the medical area risk deterring the use of critically important products. Thus, a warning label

must strike a balance between notifying users of potential dangers and not unnecessarily deterring beneficial uses. See *ibid.*

Moreover, the more warnings included in labeling, the less effective each constituent warning becomes. Warning of theoretical risks can cause more meaningful risk information to "lose its significance." 44 Fed. Reg. 37,447 (1979); accord 71 Fed. Reg. at 3935; 65 Fed. Reg. 81,083 (2000). Indeed, "[o]verwarning has the effect of not warning at all. The reader stops paying attention to excess warnings." FDA, *Write It Right* 7 (1993). Thus, there are "a number of sound reasons why the FDA may prefer to limit warnings on product labels." *Brooks* v. *Howmedica, Inc.*, 273 F.3d 785, 796 (8th Cir. 2001), cert. denied, 535 U.S. 1056 (2002).

In *Lohr*, this Court emphasized that FDA had *not* "weighed the competing interests relevant to the particular requirement in question" or "reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases." 518 U.S. at 501. Because FDA undertakes such a weighing as part of its premarket approval process, according preemptive effect to FDA's premarket approvals is fully consistent with *Lohr*.

b. Once FDA granted premarket approval for the Evergreen Balloon Catheter based on the agency's risk-benefit balancing, respondent could not have lawfully marketed a product that deviated from the approved version nor made any changes affecting the safety or efficacy of the device, including labeling changes, without first submitting a supplemental application to FDA. See 21 U.S.C. 360e(d)(6); 21 C.F.R. 814.39(a). The supplemental premarket approval process is similar to the initial PMA process. "All procedures and actions that apply to an [original application] * * * also apply to PMA supplements except that the information required in a supplement is limited to that needed to support the change." 21 C.F.R. 814.39(c).

While petitioners argue (Br. 31) that applicants may make some changes without prior FDA approval, that is true only in

very limited circumstances that do not appear to apply here. Some changes in labeling, quality controls, or manufacturing processes may go into effect before FDA review if they "enhance[] the safety of the device." 21 C.F.R. 814.39(d). As FDA recently explained in a draft guidance document, however, even those types of changes may be made without prior FDA approval only if "the manufacturer has newly acquired safety-related information" that "was not previously considered by the FDA." FDA, *Draft Guidance for Industry and FDA Staff, Modifications to Devices Subject to Premarket Approval (PMA)* 19 (Mar. 9, 2007) (Draft Guidance) <http://www.fda.gov/cdrh/ode/guidance/1584. pdf>. Unilateral changes based on information available at the time of FDA's approval could upset FDA's balance of health risks and benefits, and thus "undermine" the PMA process. *Ibid.* Indeed, it would make little if any sense to permit unilateral changes immediately following FDA's approval based on the same information that FDA had already considered.

Even if a manufacturer relies on new information to support a safety-enhancing change to a label, it still must obtain prior approval for any changes that affect both safety *and* efficacy. Draft Guidance 20. Though such a change would (in the manufacturer's view) improve a device's safety, it could also reduce health benefits, and thus affect the overall risk-benefit tradeoff. In this case, it appears that the exceptions to prior approval are beside the point, in part because petitioners' tort claims do not appear to be based on newly available information. And, in any event, the statute and regulations vest in FDA, not States or juries, the authority to accept or reject the changes, whether or not the manufacturer has put them into effect in the meantime.

c. Petitioners argue (Br. 27) that, although FDA can impose design requirements with preemptive effect by regulation, the PMA process does not impose such requirements because FDA merely approves the applicant's proposed design. That is incorrect. If FDA finds that a proposed device is not safe or effective,

it can condition its grant of premarket approval on the manufacturer's making specified changes to the device. 21 C.F.R. 814.44(e) and (f). In FDA's experience, manufacturers often agree to make such changes, even before FDA formally requires them as a condition of approval, in order to receive premarket approval. There is no meaningful basis for distinguishing between a specification imposed by regulation and the same specification imposed as a condition of premarket approval. In either case, a manufacturer could not deviate from the requirement without risking a violation of the MDA. Thus, FDA's regulations provide that federal "requirements" include not only "regulations," but also "other specific requirements applicable to a particular device." 21 C.F.R. 808.1(d).

Similarly, it makes no difference whether the approved device is identical to the one initially submitted by the applicant for approval, or was modified in the course of FDA's review. As the court of appeals explained, it would be perverse to subject respondent to greater potential tort liability on the ground that, because the device was safe and effective in the form submitted to FDA, it did not require changes or additional safeguards as a condition of premarket approval. Pet. App. 27a-28a. Whether or not the specifications were modified in the approval process, the applicant is generally barred from making changes without FDA's prior approval. Once the premarket approval process is complete, the manufacturer, with exceptions not relevant here, cannot lawfully market a product that deviates from the approved version. The specifications, as to both product and label, developed in the approval process become the requirements for lawfully marketing the device.

### B. Petitioners' Tort Claims Would Impose State-Law Requirements

Just as the premarket approval process imposes requirements, petitioners' state-law claims would impose requirements on the design and labeling of the device.

1. Petitioners argue at length (Br. 14-23) that *no* state common-law duties are "requirements" subject to preemption. As the court of appeals explained, this Court has already rejected that contention. See Pet. App. 30a-32a.

While a four-Justice plurality of the *Lohr* Court predicted that "few, if any, common-law duties have been pre-empted by this statute," 518 U.S. at 502, a majority of this Court disagreed. Writing for herself and three other Justices, Justice O'Connor "conclude[d] that state common-law damages actions do impose 'requirements' and are therefore pre-empted where such requirements would differ from those imposed by the [MDA]." *Id.* at 509. She explained that "state common-law damages actions operate to require manufacturers to comply with common-law duties." *Id.* at 510. "The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." *Ibid.* (quoting *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 247 (1959)).

Writing separately, Justice Breyer "basically agree[d] with Justice O'Connor's discussion of this point and with her conclusion." 518 U.S. at 503. Justice Breyer explained that distinguishing between a state agency regulation requiring a particular design and a jury verdict imposing liability for failure to use that design would produce the "anomalous result" of "grant[ing] greater power (to set state standards 'different from, or in addition to,' federal standards) to a single state jury than to state officials acting through state administrative or legislative lawmaking processes." *Id.* at 504. Thus, Justice Breyer concluded that, "ordinarily, insofar as the MDA pre-empts a state requirement embodied in a state statute, rule, regulation, or other administrative action, it would also pre-empt a similar requirement that takes the form of a standard of care or behavior imposed by a state-law tort action." *Id.* at 504-505.

The Court reached the same conclusion in *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504 (1992), and *Bates* v. *Dow Agro-*

*sciences LLC*, 544 U.S. 431 (2005). *Cippolone* held that "[t]he phrase '[n]o requirement or prohibition' sweeps broadly and suggests *no distinction* between positive enactments and common law; to the contrary, those words *easily encompass* obligations that take the form of common-law rules." 505 U.S. at 521 (plurality opinion) (emphases added); accord *id.* at 548-549 (Scalia, J., concurring in the judgment in part and dissenting in part). In *Bates*, this Court again held that "requirements" "reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties." 544 U.S. at 443.[1]

Petitioners err in arguing (Br. 22) that "requirements" should be read to exclude common-law requirements because, at the time Congress enacted Section 360k, this Court had not yet construed a similar provision in any other statute to include common-law requirements. That rationale would have applied with equal force in *Cippolone*, because that was the first case in which this Court construed the term "requirement" in an express preemption clause. But the meaning of a statutory term stems from its ordinary usage and statutory context, not whether it has previously been construed by this Court. Cf. *Cippollone*, 505 U.S. at 521 (plurality opinion) (explaining that the term "requirements" "plainly" and "easily" includes common-law duties).

2. Petitioners argue (Br. 19-21) that the conclusion that common-law standards of care are "requirements" is inconsistent with the statutory structure. There is no inconsistency. Petitioners assert (Br. 13) that "requirements" cannot encompass state

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[1] Petitioners rely (Br. 37) on *Bates*' statement that "an event, such as a jury verdict, that merely motivates an optional decision is not a requirement." 544 U.S. at 445. That passage does not address the question whether the substantive standard of care sought to be enforced in a common-law claim is a requirement (a question *Bates* answers in the affirmative, see *id.* at 443). Instead, it addresses the separate question whether requirements that do not directly apply to a product's label or packaging are nonetheless requirements "for labeling or packaging," as required by the statute at issue in *Bates*. See *id.* at 444-445. That question is not implicated here.

tort duties because Section 360k(b), which authorizes FDA to exempt from preemption a state or local "requirement" that satisfies certain conditions, "cannot workably be applied to damages claims." But nothing in the statute bars FDA from granting an exemption for a requirement developed at common law. FDA may grant an exemption if either (i) a state requirement is more stringent than the corresponding federal requirement, or (ii) a state requirement is "required by compelling local conditions" and compliance with the requirement would not cause the device to violate a federal requirement. 21 U.S.C. 360k(b)(1).

While it may be more difficult for a common-law requirement to satisfy the conditions for an exemption, that does not mean that FDA lacks authority to grant an exemption if a common-law requirement satisfies either of the statutory prongs. Common-law judges are not unable to impose clear requirements. Some common law rules are very clear. See, *e.g.*, *Ling* v. *Jan's Liquors*, 703 P.2d 731, 635 (Kan. 1985) (no liability at common law for furnishing liquor to intoxicated person). Common-law requirements can be clearly explained in opinions and are often clear enough for state legislators to replace a common-law requirement with one imposed by positive law. See, *e.g.*, N.Y. Gen. Oblig. § 11-101 (imposing liability for furnishing liquor in some circumstances). In any event, while petitioners assume that Congress intended to ensure the availability of an exemption for every type of "requirement" subject to preemption, that assumption does not follow from the statutory text. Even if the conditions for granting an exemption meant that some types of requirements were not eligible for exemptions, that does not mean that those requirements would somehow lose their status as requirements.[2]

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[2] FDA's regulations do not expressly identify judicial or common-law rules as a subject for exemption, but do not rule them out, either. See 21 C.F.R. 808.20(c)(1) (State or locality must identify the "statute, rule, regulation, or ordinance" for which it seeks an exemption).

Petitioners also rely (Br. 20) on 21 U.S.C. 360h(d), which provides that an FDA order requiring public notice that a device poses an unreasonable risk of substantial harm does "not relieve a person from liability under Federal or State law," including "damages for economic loss." While that provision contemplates that *some* state-law actions are not preempted, it nowhere suggests that *no* such actions are preempted. Nor does it shed light on *which* such actions are preempted, which is the question here.

The more telling contextual evidence comes from the statute's drafting history. The preemption provision in the bill initially passed by the Senate applied only to "a standard or regulation which prescribes any requirements as to" specified topics. S. Rep. No. 33, 94th Cong., 1st Sess. 72 (1975). By ultimately enacting the broader text of Section 360k(a)—which refers to "any requirement," not only a requirement prescribed by a standard or regulation—Congress rejected a provision that was limited to state positive law in favor of one that is not. Moreover, as the House Report explained, Congress's concern was that "if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened." H.R. Rep. No. 853, *supra*, at 45. That concern does not turn on the form or source of a requirement.

### C. The State-Law Requirements At Issue Here Are Different From, Or In Addition To, The Federal Requirements

The court of appeals correctly determined which of petitioners' state-law claims assert duties that are different from or in addition to federal requirements, and are therefore preempted. See Pet. App. 32a, 35a-36a.

### 1. *Common-law claims are preempted insofar as they assert that a device in its FDA-approved form is not safe or effective for use as directed in the FDA-approved labeling*

Petitioners' negligent-manufacturing claim is not preempted "to the extent it rest[s] on the allegation that the particular Evergreen Balloon catheter that was deployed during Mr. Riegel's angioplasty had not been manufactured in accordance with the PMA-approved standards." Pet. App. 35a. Such a claim would not impose an additional or different *requirement*; instead, it would provide a *remedy* for respondent's alleged failure to comply with a state law that parallels federal requirements. See 21 C.F.R. 808.1(d)(2); *Lohr*, 518 U.S. at 495; *id.* at 513 (O'Connor, J., concurring in part and dissenting in part).

In contrast, the other claims at issue here are premised on the assertion that the device, "in its present PMA-approved form, is in some way defective and therefore requires modification." Pet. App. 32a. Any judgment in petitioners' favor on those claims would necessarily rest on a finding that respondent was required, under state law, to alter the FDA-approved product specifications or labeling. As such, those state-law claims would impose requirements that are different from, or in addition to, the federal requirements.[3]

### 2. *The claims at issue here would interfere with FDA's expert balancing of health risks and benefits*

The conclusion that the MDA preempts the claims at issue here is buttressed by the extent to which those claims would interfere with FDA's expert balancing of a device's health risks

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[3] Like petitioners' negligent-manufacture claim, their express-warranty claim is not preempted because it would merely provide a remedy for the violation of a state law that parallels a federal requirement. Pet. App. 72a. The district court entered summary judgment on the merits of that claim, however, and petitioners did not appeal that aspect of the judgment. *Id.* at 6a n.3.

and benefits. In *Lohr*, the Court looked to the statute's "overarching concern that pre-emption occur only where a particular state requirement threatens to interfere with a specific federal interest." 518 U.S. at 500. Justice Breyer likewise concluded that "[i]t makes sense, in the absence of any indication of a contrary congressional (or agency) intent, to read the pre-emption statute (and the pre-emption regulation) in light of * * * basic [conflict] pre-emption principles." *Id.* at 508.

a. Permitting a state jury to impose liability on the basis that a device FDA found to be safe and effective is *not* safe or effective would clearly interfere with the agency's ability to utilize the premarket approval process to balance the risks and benefits of Class III medical devices. The MDA is a "balanced" statute designed "to assure [both] that the public is protected from unsafe and ineffective medical devices" and "that innovations in medical technology are not stifled by unnecessary restrictions." H.R. Rep. No. 853, *supra*, at 12. In keeping with the latter concern, FDA balances a device's health risks against its benefits, and approves even devices that pose significant risks if their benefits outweigh the risks. See pp. 11-13, *supra*. Thus, premarket approval reflects FDA's expert determination that a device is on balance beneficial to human health, and therefore *should* be on the market. In such circumstances, a jury's imposition of liability based on a device's FDA-approved design or label would interfere with the balance struck by Congress in the MDA, and by FDA in approving the particular device.

Consider the example Justice Breyer used in *Lohr*. See 518 U.S. at 504. If FDA approves a hearing aid with a one-inch wire, a jury's imposition of liability on the theory that a two-inch wire should have been used would conflict with FDA's expert judgment. While petitioners assert (Br. 38) that the basis for a jury verdict is not always so clear, that hardly diminishes the concern. Imprecise standards can frustrate the federal regulatory balance as much as (if not more than) clear rules. What matters is not

the precision of the state law, but its conflict with federal policy. And in this example, the conflict is clear: FDA found that the device was safe and effective in a particular form, and the jury found that it was not.

Claims that challenge a device's FDA-approved label would similarly intrude upon FDA regulation. Over-warning poses serious health risks. See pp. 12-13, *supra*. As FDA has explained, "product liability and medical malpractice lawsuits, together with increasing litigation costs, ha[ve] caused manufacturers to become more cautious and include virtually all known adverse event information [in labels], regardless of its importance." 65 Fed. Reg. at 81,083. The consequence is "to limit physician appreciation of potentially far more significant" risks. 71 Fed. Reg. at 3935. The critical importance of providing appropriate warnings for medical devices—and, in particular, the most complex and highest-risk devices—further supports the conclusion that Congress intended FDA to use its expert judgment concerning the appropriate warnings for a particular medical device, and not to permit that judgment to be second guessed by lay juries.

b. Petitioners argue (Br. 40) that there is no conflict because "PMA does not preclude a later determination that the device is not safe and effective." Petitioners note in that regard (see Br. 40-41) that FDA has authority to change its mind and to withdraw its premarket approval of a device. That point only underscores, however, that Congress charged FDA, not state juries, with the responsibility to determine whether a device remains safe and effective and, thus, whether to withdraw the agency's approval.

Manufacturers must provide extensive information to FDA following approval of a medical device, including prompt reporting of adverse events that might be related to the device. See pp. 3-4, *supra*. FDA also conducts "routine postmarket inspections" of manufacturing facilities and other sites, and receives complaints from members of the public. FDA, *Ensuring the*

*Safety of Marketed Medical Devices* 11-13, 15 (2006) <http://www.fda.gov/cdrh/postmarket/mdpi-report.pdf>. Based on all of those sources of information, FDA may withdraw premarket approval for a variety of reasons, including that the agency no longer believes that the device satisfies the requirements for premarket approval. 21 U.S.C. 360e(e)(1). When FDA has not taken that action, however, its premarket approval of the device—and the federal requirements that result from that approval—remain in effect.[4]

d. FDA's conclusion that state tort liability would undermine its ability to balance risks and benefits is similar to the agency policy judgment to which this Court deferred in *Geier* v. *American Honda Motor Co.*, 529 U.S. 861 (2000). There, as here, the agency did not merely impose minimum safety standards. *Id.* at 874-875. Instead, it determined that public safety was best served by permitting manufacturers to install a variety of different passive restraint systems in their vehicles. *Id.* at 881. The Court held that a state suit seeking to impose liability for failure to use a particular type of restraint system would stand as an obstacle to the federal agency's decision. *Id.* at 881-883; see also, *e.g.*, *Chicago & N.W. Transp. Co.* v. *Kalo Brick & Tile Co.*, 450 U.S. 311, 325, 327 (1981). So too here, imposing liability on a manufacturer for using an FDA-approved design or altering an FDA-approved label would conflict with FDA's determination that the design and label appropriately balance the health risks and benefits.

FDA's understanding of its premarket approval process, and its judgment respecting the extent to which state law would interfere with that process, are entitled to deference. As this

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[4] That does not mean that injured persons are necessarily without a remedy. Petitioners' express-warranty and negligent-manufacturing claims were not preempted. See Pet. App. 70a-72a. In any event, FDA's decision to grant and not withdraw premarket approval strongly suggests that a device is not defective.

Court explained in *Lohr*, "Congress has given the FDA a unique role in determining the scope of § 360k's pre-emptive effect." 518 U.S. at 495-496. It is FDA that makes a case-specific determination regarding the safety and effectiveness of a device, and it is FDA's approval of the design and labeling of the device that requires the manufacturer to adhere to those specifications in order to market the device. FDA's role in administering the MDA makes it "uniquely qualified to determine whether a particular form of state law 'stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.'" *Ibid.* (quoting *Hines* v. *Davidowitz*, 312 U.S. 52, 67 (1941)).

Petitioners argue (Br. 33-34) that FDA's judgment respecting the conflict between premarket approval and state tort duties is not entitled to deference because FDA changed its view on the matter in 2004, and its position is not set forth in a formal regulation. As explained in the government's petition-stage brief (at 16-17), however, the United States' earlier position was based in part on proposed regulations that FDA has since withdrawn, and its prior position is inconsistent with FDA's current understanding and application of the risk-management principles discussed above (*e.g.*, the need to prevent over-warning). Neither FDA's reasoned change in position, nor the absence of a formal agency regulation addressing the specific question presented here, negates deference. See, *e.g.*, *Auer* v. *Robbins*, 519 U.S. 452, 461-462 (1997) (deferring to agency view set forth in amicus brief); *Motor Vehicle Mfrs. Ass'n* v. *State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 41-42 (1983) (holding that agency's changed position is entitled to deference so long as the agency provides a reasoned explanation for the change).

***3. The federal and state requirements at issue here are not equivalent***

Petitioners argue (Br. 39) that their claims are not preempted because they are based on duties equivalent to federal statutory requirements for a Class III device, such as the prohi-

bition against misbranding and the requirement of reasonable assurance that a device is safe and effective when used in accordance with its labeling.

That claim was neither pressed nor passed upon in the court of appeals. Nor did petitioners raise it in their petition for a writ of certiorari. Thus, that claim is not properly before this Court. See, *e.g.*, *Adickes* v. *S.H. Kress & Co.*, 398 U.S. 144, 147 n.2 (1970). Indeed, it would make little sense for this Court to undertake, in the first instance, to determine the elements of petitioners' state-law causes of action and to compare them to federal statutory and regulatory requirements. Cf. *Bates*, 544 U.S. at 447 (remanding for the court of appeals to undertake that task).[5]

In any event, petitioners' argument is wrong. In *Lohr*, this Court held that common-law claims that allege violations of FDA regulations are not preempted. 518 U.S. at 495. The court explained that "a damages *remedy* does not amount to the additional or different '*requirement*' that is necessary under the statute." *Ibid.* (emphases added). Significantly, however, the only requirements at issue there were FDA's "general" regulations applicable to "every medical device." *Id.* at 497-498.

Here, in contrast, the relevant federal "requirements" are not merely the general standards for premarket approval (such as safety and effectiveness). Instead, as discussed above, they include the specific design and labeling requirements imposed as part of the PMA process. A state-law finding of liability for not modifying the FDA-approved design or label would conflict with those specific requirements, because it would be based on a determination that an FDA-approved design was not safe or effective, or an FDA-approved label was inadequate.

*Bates* is inapposite for similar reasons. In that case, this Court construed the preemption provision of the Federal Insecti-

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[5] The United States' petition-stage brief (at 14-15) pointed out that petitioners had not preserved a claim that the state and federal requirements were equivalent. In their supplemental brief, petitioners did not dispute that point.

cide, Fungicide, and Rodenticide Act (FIFRA), which provides that a State "shall not impose or continue in effect any requirements for labeling or packaging in addition to or different from those required under this subchapter." 7 U.S.C. 136v(b). This Court held that FIFRA would not preempt the plaintiffs' state failure-to-warn claim if the elements of that claim were substantively equivalent to FIFRA's prohibition on the sale of "misbranded" products. 544 U.S. at 447.

This case is fundamentally different from *Bates* because, under FIFRA, the Environmental Protection Agency (EPA) did not evaluate either the product's efficacy or the accuracy of statements about efficacy in the proposed labeling. *Bates*, 544 U.S. at 440. Because EPA had never "passed on the accuracy of" the relevant statements in the product's label, it had done nothing to "further refine [its] general [misbranding] standards in any way that [wa]s relevant to [the plaintiffs'] allegations" in *Bates*. *Id.* at 440, 453 n.27. Here, in contrast, FDA determined that there is reasonable assurance that the device is safe and effective in its current form, and that its labeling is accurate. Morever, FIFRA, unlike the MDA, does not have a comprehensive goal of "uniformity," but rather "authorizes a relatively decentralized scheme that preserves a broad role for state regulation." *Id.* at 450.

### D. Preemption Does Not Turn On Whether State Requirements Also Apply To Matters Other Than Medical Devices Intended For Human Use

Petitioners argue (Br. 34-36) that the common-law duties on which they rely are not preempted because they apply to matters other than medical devices intended for human use. That contention is incorrect.

1. Section 360k(a) provides that "no State or political subdivision of a State may establish or continue in effect *with respect to a device intended for human use* any requirement * * * which is different from, or in addition to, any requirement applicable under this chapter to the device" (emphasis added). Con-

trary to petitioners' assumption, the phrase "with respect to a device intended for human use" does not mean that only those requirements that apply *exclusively* to devices intended for human use are preempted. That phrase does not follow and modify the term "requirement." Instead, it follows and modifies the phrase "no State * * * may establish or continue in effect." Thus, it means that state requirements that apply both to devices intended for human use and to other matters are not preempted in their entirety, but instead are preempted only insofar as they apply "with respect to" devices intended for human use.

Petitioners' contrary reading is illogical. A state law's interference with federal requirements for devices intended for human use is in no way lessened by the state law's application to other matters. There is, for example, no reason that Congress would want to preempt a state statute that imposes design requirements on devices intended for human use, but to exempt altogether a state statute that imposes the same design requirements on devices intended for both human and animal use. In either case, Congress has an identical interest in preempting the statute with respect to medical devices intended for human use. The same is true of a common law duty that applies to, but is not limited to, medical devices intended for human use. Compare *Morales* v. *TWA*, 504 U.S. 374, 386 (1992).

FDA's regulations are consistent with that common-sense reading of the statutory text. They explain that the statute preempts state requirements "whether established by statute, ordinance, regulation, *or court decision*." 21 C.F.R. 808.1(b) (emphasis added). Petitioners rely (Br. 36) on a provision stating that the statute does not preempt "State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices." 21 C.F.R.

808.1(d)(1). When FDA proposed that regulation, it explained that its intent was to exclude from preemption "requirements of general applicability that relate *only incidentally* to medical devices," such as "general fire and electrical codes." 42 Fed. Reg. 30,384 (1977) (emphasis added); see *ibid.* (same). Neither the regulatory text nor the preamble states that general tort duties of care fall outside the scope of preemption. Unlike fire codes or restrictions on unfair trade practices, such duties do not relate only incidentally to devices. Instead, they directly regulate every aspect of the device itself, including its very design.

The more relevant regulation is 21 C.F.R. 808.1(d)(6)(ii). Under that provision, "a State or local requirement prohibiting the manufacture of adulterated or misbranded devices" is "[g]enerally" not preempted, but is preempted when it "has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement." As discussed, petitioners' tort claims would have precisely that effect because any imposition of liability would be based on a finding that the FDA-approved design or labeling is inadequate in some respect. Indeed, a jury verdict or common-law judge's opinion can be understood as taking a general legal rule and applying it in a way that establishes a substantive requirement for the specific device at issue.

A contrary reading of the statute or regulations would effectively exempt all common-law claims (and many positive-law claims) from preemption. Petitioners have identified no general common-law duties that apply only to medical devices intended for human use, and the United States is aware of none. Petitioners' position is thus difficult to square with the regulations' determination that requirements "established by * * * court decision," as well as general requirements that "ha[ve] the effect of establishing a substantive requirement for a specific device," are preempted. 21 C.F.R. 808.1(b) and (d)(6)(ii). In any event, FDA's interpretation of its regulations is entitled to deference. See, *e.g.*, *Auer*, 519 U.S. at 461-462.

2. Nor can petitioners' position be reconciled with this Court's decision in *Lohr*. Providing the decisive fifth vote, Justice Breyer rejected the *Lohr* plurality's view that "future incidents of MDA pre-emption of common-law claims will be 'few' or 'rare.'" 518 U.S. at 508. As Justice Breyer explained, it would make little sense to distinguish between a state agency regulation requiring a particular hearing-aid design and "a state-law tort action that premises liability upon the defendant manufacturer's failure to use [that design] (*say, an award by a jury persuaded by expert testimony that use of a [different design] is negligent*)." *Id.* at 504 (emphasis added). Under petitioners' position, however, that state-law negligence action would not be preempted, because the common-law tort of negligence is not limited to medical devices intended for human use.

Petitioners rely (Br. 35) on a portion of the *Lohr* majority opinion stating that "the general state common-law requirements in this suit were not specifically developed 'with respect to' medical devices," and therefore were "not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements." 518 U.S. at 501. In context, that discussion cannot mean that no general common-law requirements are preempted. That conclusion would be inconsistent with Justice Breyer's decisive concurrence.

Instead, the relevant discussion is best read as reflecting the types of federal and state requirements at issue in *Lohr*. The Court was addressing whether "*general* federal regulations governing the labeling and manufacture of all medical devices" preempted *general* state tort duties. See 518 U.S. at 497 (emphasis added). Here, in contrast, the question is whether FDA's device-specific PMA preempts a State's application of its general tort duties to a specific device. Because this case involves a device-specific federal requirement, it is logical to consider the state requirements at the same level of specificity. Indeed, one must

do so in order to understand the extent to which the state requirements would interfere with the federal ones.

### E. The Presumption Against Preemption Does Not Control This Case

Petitioners invoke (Br. 21) the presumption against preemption, asserting this the Court should refuse to find that state tort claims are preempted in the absence of clear evidence of congressional intent. As a majority of this Court recognized in *Lohr*, however, Congress manifested the requisite intent to preempt common-law tort duties that are different from, or in addition to, federal requirements. See p. 16, *supra*. And, as discussed above, the state claims at issue here would clearly interfere with the federal requirements imposed by the PMA process, as they seek to impose liability on respondent for using an FDA-approved design and label.

Moreover, Congress delegated to FDA the responsibility to administer Section 360k's express preemption provision. Accordingly, FDA's judgment that petitioners' claims are preempted is entitled to "substantial weight." *Lohr*, 518 U.S. at 496.

## CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted.

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IN THE

# Supreme Court of the United States

CHARLES R. RIEGEL AND DONNA S. RIEGEL,
*Petitioners,*

v.

MEDTRONIC, INC.,
*Respondent.*

**On Writ of Certiorari to the United States Court of Appeals for the Second Circuit**

## BRIEF OF AARP, NATIONAL WOMEN'S HEALTH NETWORK, U.S. PUBLIC INTEREST RESEARCH GROUP, AND NATIONAL RESEARCH CENTER FOR WOMEN & FAMILIES AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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August 27, 2007

## QUESTION PRESENTED

Whether the express preemption provision of the Medical Device Amendments of 1976, which amended the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), preempts state-law claims seeking damages for injuries caused by medical devices that received premarket approval from the Food and Drug Administration.

## TABLE OF CONTENTS

Page

QUESTION PRESENTED ..... i

TABLE OF AUTHORITIES ..... iv

INTEREST OF *AMICI CURIAE* ..... 1

BACKGROUND ..... 2

SUMMARY OF ARGUMENT ..... 5

ARGUMENT ..... 6

I. PREMARKET APPROVAL PROVIDES A LIMITED SCREENING OF MEDICAL DEVICES THAT IS INADEQUATE AND NOT INTENDED TO REPLACE STATE TORT LAW ..... 6

A. Premarket Approval Applies A Generic Safety Standard Based On Limited Device Testing Reviewed By Burdened Regulators ..... 7

B. Premarket Approval Provides Negligible Continuing Oversight And Permits Design, Manufacture, And Label Changes With Either Expedited FDA Review Or No Review At All ..... 14

II. THE TORT SYSTEM PROVIDES REMEDIES AND INCENTIVES NECESSARY TO PROTECT THE PUBLIC AND TO COMPENSATE PATIENTS INJURED BY DEFECTIVE MEDICAL DEVICES THAT RECEIVED PREMARKET APPROVAL ..... 18

A. By Uncovering Information About Defective Medical Devices, Litigation Spurs Improvements In The Medical Device Industry And The FDA ..... 18

B. Litigation Compensates Victims Of Defective Medical Devices ..... 26

CONCLUSION ..... 30

## TABLE OF AUTHORITIES

Page

CASES

*Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005) ..... 9, 17, 18, 21

*Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) ..... 17, 26, 27

*Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529 (D.C. Cir. 1984) ..... 18

*Guidant Corp. Implantable Defibrillators Prod. Liab. Litig., In re*, MDL No. 05-1708 (DWF/AJB), Civil No. 06-25 (DWF/AJB), 2007 WL 1725289 (D. Minn. June 12, 2007) ..... 20, 22, 23

*Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) ..... 2, 3, 4, 5, 6, 11, 21

*Medtronic, Inc. Implantable Defibrillators Litig., In re*, 465 F. Supp. 2d 886 (D. Minn. 2006) ..... 20-21, 25, 26

*O'Gilvie v. International Playtex, Inc.*, 821 F.2d 1438 (10th Cir. 1987) ..... 27

*Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984) ..... 27

*Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002) ..... 26

*St. Jude Med., Inc. Silzone Heart Valves Prod. Liab. Litig., In re*, No. MDL 01-1396 JRTFLN, 2004 WL 45503 (D. Minn. Jan. 5, 2004) ..... 21, 24, 25

*Sulzer Hip Prosthesis & Knee Prosthesis Liab. Litig., In re*:

268 F. Supp. 2d 907 (N.D. Ohio 2003) ..... 29, 30

455 F. Supp. 2d 709 (N.D. Ohio 2006) ..... 20, 28

STATUTES, REGULATIONS, AND RULES

Federal Insecticide, Fungicide, and Rodenticide Act, 7 U.S.C. §§ 136 *et seq.* ..... 9

Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296 ..... 12

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Preamble, 90 Stat. 539 ..... 21, 27

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## INTEREST OF *AMICI CURIAE*[1]

AARP is a non-profit, non-partisan organization with more than 39 million members, dedicated to addressing the needs and interests of people aged 50 and older. It promotes independence, dignity, and purpose for older persons; sponsors research on aging; provides educational programs, publications, and member benefits; and represents the concerns of older persons before government bodies. As the largest membership organization representing the interests of older persons, AARP has long supported laws and public policies designed to protect its members' rights and to preserve the availability of legal redress when they are harmed in the marketplace.

The National Women's Health Network improves the health of all women by influencing policy and supporting informed consumer decision-making. The Network is supported by 8,000 individual and organizational members and accepts no financial support from pharmaceutical companies, tobacco companies, or device manufacturers. Since it was founded in 1975, the Network has worked to ensure that safe drugs, devices, and medical procedures are available to all women. The Network believes that effective state tort law remedies are necessary to protect women from dangerous medical devices.

U.S. Public Interest Research Group ("U.S. PIRG"), the federation of state Public Interest Research Groups, is a national, non-profit advocacy group with more than one million members around the country. Its mission is to protect the interests of consumers and ordinary citizens using the tools of investigative research, media reports, grassroots organizing, legislative and public policy advocacy, and litigation. The ability of States to protect the

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[1] Pursuant to Supreme Court Rule 37.6, counsel for *amici* represent that they authored this brief and that no entity other than *amici*, their counsel, or their members made a monetary contribution to its preparation or submission. All parties have consented to the filing of this *amici* brief, and letters reflecting their blanket consent to the filing of *amicus* briefs in this case are on file with the Clerk.

health and well-being of their residents has been a long-standing area of concern to U.S. PIRG.

The National Research Center for Women & Families is a non-profit, nonpartisan organization dedicated to improving the health and safety of women, children, and families, by using objective, research-based information to encourage new, more effective programs and policies. The Center gathers and analyzes information and translates it into clearly presented facts and policy implications that are made widely available to the public, the media, and policy makers.

*Amici* have participated as an *amicus curiae* in numerous cases opposing federal preemption of state and local laws that provide important consumer protections.

## BACKGROUND

"To provide for the safety and effectiveness of medical devices intended for human use," Congress enacted the Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 ("MDA"). *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 474 (1996); *id.* at 491 (Stevens, J., plurality) ("[T]he primary issue motivating the MDA's enactment [was] the safety of those who use medical devices.").

Before 1976, the federal Food and Drug Administration ("FDA") could regulate drugs, but not medical devices. A series of high-profile failures of medical devices, most notably the Dalkon Shield, a defective intrauterine device responsible for at least 18 deaths and thousands of serious injuries, led to calls for increased consumer protection against such dangerous devices. *See* S. Rep. No. 94-33, at 1-2 (1975), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1070-71.[2] In response, Congress passed the MDA, which provided the FDA with limited new authority over the medical device industry. Among other provisions, the MDA created

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[2] *See also* Morton Mintz, *Questions Arose Early on Contraceptive's Safety*, Wash. Post, Apr. 7, 1985, at A1 (describing how defects in the Dalkon Shield's design caused infections in thousands of women and birth defects in their children).

a premarket approval ("PMA") process designed to prevent dangerous medical devices from reaching the market. *See* Pub. L. No. 94-295, § 2, 90 Stat. 552 (codified as amended at 21 U.S.C. § 360e).

This PMA process is part of a three-tiered regime that provides general regulation of the "vast array of medical equipment [f]rom bedpans to brainscans," *Lohr*, 518 U.S. at 476 (alteration in original; internal quotation marks and citation omitted). The MDA requires that the FDA classify every medical device into one of three categories. Class I devices, like rubber gloves, are the least risky devices and are subject to only basic requirements, such as that the device not be misbranded or adulterated. *See* 21 U.S.C. § 360c(a)(1)(A). Class II devices, such as hearing aids, are more likely to harm consumers, so the FDA may pass regulations subjecting these devices to additional controls, such as requiring specific warning labels. *See id.* § 360c(a)(1)(B); 21 C.F.R. § 801.430. In most cases, manufacturers do not need to obtain approval from the FDA before marketing Class I or Class II medical devices to consumers.[4]

A Class III medical device, like the balloon catheter at issue in this case, is one that either presents "a potential unreasonable risk of illness or injury" or is "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." 21 U.S.C. § 360c(a)(1)(C). Before manufacturers can market these devices, they must receive permission from the FDA, through either the premarket notification or the premarket approval process. The premarket notification process requires the manufacturer to submit a form to the FDA describing the device and explaining how it is substantially equivalent to an FDA-approved device that is already on the market. *See id.* §§ 360c(f)(1)(a),

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[4] *See* FDA, *Medical Device Exemptions 510(k) and GMP Requirements*, http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpcd/315.cfm (last visited Aug. 23, 2007).

360e(b)(1)(B); 21 C.F.R. § 807.92. If the FDA finds, on the basis of this information, that the device is substantially equivalent to an approved device, it can be marketed. *See Lohr*, 518 U.S. at 478-79.

If no substantial equivalent exists, the device can be sold only upon the FDA's premarket approval, which requires a more detailed application from the manufacturer and a lengthier review of that application by the FDA. *See* 21 C.F.R. § 814.20. In *Lohr*, this Court held that premarket notification does not preempt duties traditionally enforced by state tort law. *See* 518 U.S. at 501-02. This case involves the preemptive effect of the second Class III approval process, the PMA.

The MDA includes a narrow, express preemption provision that, "with respect to a device intended for human use," preempts a state "requirement (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter." 21 U.S.C. § 360k(a). FDA regulations implementing § 360k(a) provide that an FDA requirement has preemptive effect only when it establishes a device-specific "counterpart" to a "divergent" state-law requirement that is "specific" to a particular device. 21 C.F.R. § 808.1(d). The MDA does not preempt requirements of "general applicability . . . to other products." *Id.*

For example, FDA regulations impose specific design requirements for certain laser devices, *see id.* § 886.4392, which would preempt contrary or additional state regulation. The FDA may also exempt state requirements from the preemptive effect of a federal requirement, *see* 21 U.S.C. § 360k(b), and the exemptions granted reflect the FDA's narrow understanding of § 360k(a)'s preemptive effect. What this Court recognized in *Lohr* remains true today: "the FDA has never granted, nor, to the best of our knowledge, even been asked to consider granting, an exemption for a state law of general applicability; all 22

existing exemptions apply to excruciatingly specific state requirements regarding the sale of hearing aids." 518 U.S. at 499-500; *see* 21 C.F.R. §§ 808.53-808.101.

## SUMMARY OF ARGUMENT

**I.** Congress enacted the MDA to prevent manufacturers from introducing new, untested, and potentially dangerous medical devices to doctors and patients, not to provide a comprehensive safeguard from defective products. While it requires device makers to conduct some testing and to provide a "reasonable assurance" of product safety, the PMA process is based on limited information, which restricts its depth and scope. The FDA does not routinely require controlled clinical trials, is unable to subpoena information from manufacturers, has no authority or resources to conduct independent testing, and cannot compare the safety or efficacy of a submitted device to others on the market. Furthermore, PMA applications enjoy a presumption in favor of approval; if an enumerated reason for denial does not apply, the statute and implementing regulations require premarket approval.

This limited premarket review is a one-time licensing scheme and involves very little continuing regulation after a device is approved and in use by doctors and patients. Defective devices with premarket approval typically remain on the market until the manufacturer commences a voluntary recall, and the FDA neither compensates victims nor sanctions device makers.

**II.** The traditional state tort system provides manufacturers with safety incentives, the public with information about defective devices, and victims with compensation for their injuries. The PMA system, at best, can only supplement—and cannot supplant—those traditional functions of state tort liability. When dangerously defective devices receive premarket approval and injure scores of patients, litigation reinforces the purposes of the MDA—improving the safety and effectiveness of medical devices by uncovering flaws, encouraging compliance with FDA standards, and compensating victims.

Premarket approval is an important process intended to end an era in which manufacturers marketed potentially dangerous medical devices without any meaningful testing and with no assurances of safety. But, while the PMA process provides minimum safeguards, it is insufficient to replace the comprehensive and continuous safety incentives, information disclosure, and victim compensation that state tort law has traditionally provided.

## ARGUMENT

### I. PREMARKET APPROVAL PROVIDES A LIMITED SCREENING OF MEDICAL DEVICES THAT IS INADEQUATE AND NOT INTENDED TO REPLACE STATE TORT LAW

As this Court recognized in *Lohr*, "the statutory framework" and "the structure and purpose of the statute as a whole," revealed in the text and "the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law," are relevant in interpreting the MDA's preemption provision. 518 U.S. at 486 (internal quotation marks and citations omitted). Such a reasoned understanding reveals that the PMA process was established as, and remains, one where "the agency faces limitations that result from many factors, including the agency's legal mandate, pressures from industry, pressures from advocacy groups, funding constraints, and varied political pressures." Richard A. Deyo, *Gaps, Tensions, and Conflicts in the FDA Approval Process: Implications for Clinical Practice*, 17 J. Am. Board Fam. Prac. 142, 143 (2004).

PMA is based upon partial information that is reviewed by a constrained and conflicted FDA. That review merely screens new Class III medical devices and licenses for market those that appear to meet a generic standard of safety and efficacy. The FDA does not apply a single specific safety standard or requirement to a device before its approval. And PMA is a one-time review, with no reevaluation and very little FDA oversight once a device

reaches doctors and patients. Due to the limitations inherent in the PMA process, the FDA cannot guarantee that defective, dangerous, and deadly medical devices will not reach consumers. The limited PMA process, which was intended to promote consumer safety, is entirely inadequate to replace the long-standing safety incentives and consumer protections provided by state tort law.

### A. Premarket Approval Applies A Generic Safety Standard Based On Limited Device Testing Reviewed By Burdened Regulators

1. Limits on the information that manufacturers must submit to the FDA during the PMA process restrict the scope and depth of the FDA's review. A manufacturer's PMA application includes information on the device, any investigations conducted into its safety and efficacy, and its manufacture, processing, and labeling. *See* 21 U.S.C. § 360e(c)(1); 21 C.F.R. § 814.20. The FDA lacks authority to subpoena additional information from the device maker or independently to obtain safety data. *See* Teresa Moran Schwartz, *Prescription Products and the Proposed Restatement (Third)*, 61 Tenn. L. Rev. 1357, 1386 (1994).

Those constraints inhibit the FDA's review. First, the testing of device safety reported in the PMA application can be quite limited, and many applications are approved despite the lack of any controlled clinical study. *See* Scott D. Ramsey et al., *The Limited State of Technology Assessment for Medical Devices: Facing the Issues*, 4 Am. J. Managed Care SP188, SP190 (1998) ("Studies do not necessarily have to be randomized or have a control population, although the FDA encourages controlled clinical investigations. In practice, most new device evaluations are neither randomized nor controlled studies."). Whereas the safety of new *drugs* must be demonstrated by at least two controlled clinical trials, *device* manufacturers need submit only a single clinical study, and controls are not mandatory. *See* Michael D. Green & William B. Shultz, *Tort Law Deference to FDA Regulation of Medical Devices*, 88 Geo. L.J. 2119, 2136 (2000); *see also* Deyo, 17 J. Am.

Board Fam. Prac. at 144 (recognizing that the FDA's approach to approving medical devices is "less stringent" than that applied to new drug approvals).

Further, that limited clinical testing can be unreliable. As two former editors-in-chief of the *New England Journal of Medicine* have observed, "companies now often insist on controlling how the research is done and reported, and whether the results will even be published at all," under "financial arrangements with academic medical centers and their faculties . . . that threaten the objectivity and credibility of clinical research." Marcia Angell & Arnold S. Relman, Op-Ed, *Prescription for Profit*, Wash. Post, June 20, 2001, at A27. The FDA has no authority to conduct or commission independent investigations into device safety and must typically rely on study results provided in the manufacturer's application.

Second, a PMA application discloses nothing more than the device design, manufacture, and labeling that the manufacturer chooses to submit for approval. *See* 21 U.S.C. § 360e(c)(1). Thus, the manufacturer is not required to submit information about development of the device, including any alternative designs, manufacturing methods, and labeling possibilities that the manufacturer considered, but rejected. Nor does the FDA have the authority to subpoena these and other records from the manufacturer, and, "therefore, in most instances cannot compel the disclosure of information about product risks." Schwartz, 61 Tenn. L. Rev. at 1386.

**2.** The PMA process applies a generic safety standard; it does not impose device-specific safety requirements demanding particular design, manufacture, or labeling. The FDA merely evaluates whether the manufacturer has provided a "reasonable assurance" that its device meets the general safety standard applicable to *all* medical devices. *See* 21 U.S.C. § 360e(c)(3).

When the FDA determines that a manufacturer has submitted a complete PMA application according to the application criteria, it evaluates the application to deter-

mine whether the device maker has made "a showing of reasonable assurance" that the device is safe and effective. *Id.* § 360e(d)(2)(A), (B). The factors to which the FDA looks in determining safety apply generally to all Class III devices, as well as to the classification decision for any type of medical devices and to the establishment of performance standards for any Class II device. *See* 21 C.F.R. § 860.7. Some consider this generic review to be rigorous because manufacturers devote considerable time to preparing an application and because the FDA takes months to review the application for compliance. But, as the government once argued to this Court, time is no substitute for specificity: the FDA does "not set out specific requirements for the particular device" and, instead, "the manufacturer may select any design, manufacturing, and labeling features that will satisfy the general minimum standards in the Act and regulations." U.S. Amicus Br. at 16, *Smiths Indus. Med. Sys., Inc. v. Kernats*, No. 96-1405, *cert. denied*, 522 U.S. 1044 (1998).[4]

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[4] For more than 25 years after the MDA's enactment, the government opposed PMA preemption, as it did in *Kernats*. As the FDA's former Chief Counsel explained, "[s]ince the passage of the [MDA], it has been the agency's position that the scope of preemption under section 521 should be interpreted narrowly, with a presumption against preemption," and that "preemption is limited to instances where there are *specific* FDA requirements applicable to a particular device or class of devices." Margaret Jane Porter, *The Lohr Decision: FDA Perspective and Position*, 52 Food & Drug L.J. 7, 7 (1997) (emphasis added). Beginning in 2004, the government reversed course and advocated for preemption in the lower courts. *See, e.g.*, U.S. Amicus Br., *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004) (No. 02-4597). Because preemption analysis turns on congressional intent, it is unpersuasive for the current Administration to purport to have engaged in a 180-degree reassessment of congressional intent after a quarter-century of settled administrative practice. *Cf. Bates v. Dow AgroSciences LLC*, 544 U.S. 431, 449 (2005) (calling "particularly dubious" the assertion that the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA") contained a "nonambiguous command to pre-empt [certain] tort claims" where the United States had argued to the contrary five years earlier); *see also* Oral Arg. Tr., *Bates v. Dow AgroSciences LLC*, No. 03-388, 2005 WL 148903, at *37-*39 (Jan. 10, 2005).

Instead of specific requirements, there is a presumption in favor of approval unless the FDA finds that a specifically enumerated cause for denial applies. *See* 21 C.F.R. § 814.44(d)(1) ("FDA will issue to the applicant an order approving a PMA if none of the reasons in § 814.45 for denying approval to the application applies."). If a PMA application meets the generally applicable level of safety and efficacy, the FDA is required by law to approve it—even if there are safer devices on the market and the FDA knows the device's safety is suboptimal. Indeed, the FDA did not deny *any* original PMA application during fiscal years 1993 through 2005, the last year for which annual reporting is available. A majority of the original PMA applications—including Medtronic's Evergreen Balloon Catheter—received the FDA's generic approval letter.[5]

When an application "substantially"—but not fully—meets the PMA requirements, the FDA issues an "approvable letter." 21 C.F.R. § 814.44(e). The approvable letter informs the manufacturer that its PMA application can be approved upon the submission of missing information, an inspection of its manufacturing facilities, a restriction on the sale or distribution of the device (*i.e.*, requiring distribution by licensed professionals), or an agreement to postapproval duties that typically involve continued testing, reporting, and recordkeeping. *See id.*; *see also id.* § 814.82.[6] An approvable letter imposes no

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[5] The FDA last denied an original PMA application in 1992, when it issued four denials. From 1992 through 2005, the FDA made 889 overall "approval decisions"—including 507 approvals, 248 approvable letters, 130 not approvable letters, and the 4 denials in 1992. *See* Office of Device Evaluation, *Annual Report Fiscal Year 2005*, at 36; Office of Device Evaluation, *Annual Report Fiscal Year 2004*, at 41; Office of Device Evaluation, *Annual Report Fiscal Year 2000*, at 35; Office of Device Evaluation, *Annual Report Fiscal Year 1996*, at 17. (Office of Device Evaluation Annual Reports are available at http://www.fda.gov/cdrh/ode/odeannualreports.html.)

[6] Because an approvable letter cannot dictate specific design, manufacturing, or labeling requirements (aside from requiring the prominent display of the manufacturer's proposed warning), the court below was wrong to assert that an "approvable letter" enables the FDA "to

device-specific requirements, however, and merely provides a means to facilitate approval where a substantially complete PMA application falls just shy of the minimum requirements for approval. It is a tool intended to avoid cycles of denial and resubmission; a manufacturer is free to decline the approvable letter's information requests or postapproval conditions and to resubmit an entirely new PMA application. *See id.* § 814.44(e)(2)(ii), (iii). Alternatively, where the FDA believes that an enumerated ground for denial may keep an application from being approved, it may issue a "not approvable" letter that describes the deficiency and provides the opportunity to amend the PMA application. *See id.* § 814.44(f).

Regardless of the precise path a device takes to premarket approval, the device will never need to meet a device-specific requirement. The manufacturer always has the freedom to choose any design, manufacturing method, or labeling, so long as it meets the generic minimum safety standard. Thus, in this case, the FDA "did not 'require' Medtronic's [catheter] to take any particular form for any particular reason." *Lohr*, 518 U.S. at 493.

**3.** The FDA conducts the PMA process with minimal resources and suffers from conflicts of interest. The FDA receives limited funding from Congress and depends increasingly on both industry funding and advisory panel members with financial and professional interests in the

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require the device to take a particular form in order to be approved as safe and effective." Pet. App. 26a. In any event, the FDA did not issue an approvable letter in this case. *See id.* at 27a. Moreover, the court below conflated the limited "conditions of approval" that are included in an approvable letter with the FDA's power to condition PMA on a manufacturer meeting device-specific performance standards promulgated through notice-and-comment rulemaking (*see* 21 C.F.R. §§ 861.1, 861.20). *See* Pet. App. 26a-28a. No device-specific performance standards applied to Medtronic's Evergreen Balloon Catheter, and thus its PMA was not conditioned on meeting such a standard. The court below wrongly suggested that the mere *authority* to issue device-specific performance standards after notice-and-comment rulemaking preempts state tort law even where no such performance standards have been promulgated. *See id.* at 27a-28a.

device industry. As Judge Pooler recognized in dissent below, "the FDA may not have adequate resources to genuinely ensure that devices are safe or to properly and effectively reevaluate approvals as new information becomes available." Pet. App. 48a. The FDA is under enormous pressure and, as Dr. David Feigal, the former head of the FDA's Center for Devices and Radiological Health, has admitted, "'[the FDA has] to make choices about which things to work on because of shrinking resources.'" Robert J. Cohen & Scott Orr, *Often the Patient Is the Last to Know*, Star-Ledger (Newark, N.J.), Aug. 11, 2002, at 1. Congress nonetheless has reinforced its intent that the FDA license devices as quickly as possible, stating in the Food and Drug Administration Modernization Act of 1997, Pub. L. No. 105-115, 111 Stat. 2296, that the FDA should approve or deny a PMA application "[a]s promptly as possible," generally no later than "one hundred and eighty days after the receipt of an application." 21 U.S.C. § 360e(d)(1)(A).

Because the FDA has limited resources from congressional appropriations, it is perhaps unsurprising that the agency turns to individuals with interests in the regulated industry and, more recently, to industry financing of the regulatory process to fill the gaps in its drug and device-approval processes. In a recent survey, FDA scientists "reported significant interference with the FDA's scientific work." Union of Concerned Scientists, *Voices of Scientists at FDA: Protecting Public Heath Depends on Independent Science* at 1 (2006), *available at* http://www.ucsusa.org/scientific integrity/interference/fda-scientists-survey-summary.html. Sixty percent of the scientists surveyed knew of cases where commercial interests inappropriately influenced FDA approvals or other decisions. *See id.* at 2. One-fifth reported being "'asked explicitly by FDA decision makers to provide incomplete, inaccurate or misleading information to the public, regulated industry, media, or elected/senior government officials.'" *Id.*

The FDA's use of panels of "outside scientists" to advise the agency on whether to approve new medical devices

and drugs is especially plagued by conflicts of interest. A recent study of drug advisory committees found that almost one-third of the scientists on these panels "had financial interests greater than $50,000" in the company whose products they were responsible for evaluating. Jonathan D. Rockoff, *FDA Seeks to Limit Conflicts of Interest; Rules Would Restrict Outside Advisors with Industry Ties*, Baltimore Sun, Mar. 22, 2007, at 1A. For more than one-fifth of these panels, a majority of the scientists reportedly had a conflict of interest. *See* Peter Lurie et al., *Financial Conflict of Interest Disclosure and Voting Patterns at Food and Drug Administration Drug Advisory Committee Meetings*, 295 J. Am. Med. Ass'n 1921, 1924 (2006). On nearly three-quarters of the panels, at least one of the scientists was reported to have a conflict of interest. *See id.* A scientist who has served on FDA panels reported that those with conflicts of interest sometimes influence the panel's advice, remarking "they can be very persuasive." Rockoff, *FDA Seeks to Limit Conflicts of Interest* (internal quotation marks omitted).

The recent enactment of "user fees," through which the regulated industry now funds a significant portion of the regulatory process, has only exacerbated these conflicts of interest. *See* Medical Device User Fee and Modernization Act of 2002, Pub. L. No. 107-250, § 102, 116 Stat. 1588, 1589 (codified at 21 U.S.C. § 379i). Critics argue that

> the user fees create an obvious conflict of interest. So much of the FDA budget now comes from the industry it regulates that the agency must be careful not to alienate its corporate "sponsors." FDA officials believe they remain careful but concede that user fees have imposed pressures that make review more difficult[.]

Deyo, 17 J. Am. Board Fam. Prac. at 146 (footnote omitted). In permitting the regulated industry to exercise such influence over PMA decisions, Congress could not have intended the FDA to act as the final arbiter of device

safety, foreclosing recovery by consumers subsequently injured by that industry's defective medical devices.

### B. Premarket Approval Provides Negligible Continuing Oversight And Permits Design, Manufacture, And Label Changes With Either Expedited FDA Review Or No Review At All

1. Congress intended premarket approval to be a one-time licensing scheme, and therefore provided the FDA with little authority to monitor and regulate devices that have received PMA. Today, the FDA's postmarket monitoring programs are deeply flawed and rely almost exclusively on a self-reporting honor system among manufacturers. As the leading industry group has stated, device manufacture is "a continuous, iterative process," where "actual use of devices by practitioners in the clinical setting typically spurs additional refinements and improvements." Elizabeth D. Jacobson, *AdvaMed's Written Testimony on The Critical Path White Paper at Science Board to the Food and Drug Administration* 3 (Apr. 22, 2004). But, once a device is approved for marketing, the FDA exercises minimal oversight.

The near-total lack of post-PMA device regulation provided for by the original MDA demonstrates that Congress did not establish a comprehensive, continuous review process for Class III medical devices. Under the original MDA, which included the preemption provision at issue here, "device manufacturers [were] not required to notify FDA when they [became] aware of a death, injury, or hazard caused by a medical device." Statement of Franklin A. Curtis, Associate Director, Human Resources Division, United States General Accounting Office, Before the House Committee on Energy and Commerce, Subcommittee on Health and the Environment, on the Federal Regulation of Medical Devices, 98th Cong., at 5 (Feb. 24, 1984), *available at* http://archive.gao.gov/d40t12/123484.pdf. A report to Congress indicated that, while "[t]he effectiveness of FDA's regulation of medical devices depends largely on the quality of its information,"

once devices received approval there were "major deficiencies that hinder the development of a useful medical device database" to monitor for dangerous product defects. General Accounting Office, *Comptroller General's Report to Congress; Federal Regulation of Medical Devices: Problems Still To Be Overcome* at ii (GAO/HRD-85-53, 1983).

Nor do the modest improvements to the FDA's postmarket surveillance provide sufficient protection for consumers.[7] Current postmarket surveillance relies, almost entirely, on an honor system under which manufacturers are expected to forward defect and injury reports to the FDA. The FDA has admitted that the "passive nature of these systems" results in "severe underreporting." Center for Devices and Radiological Health, *Ensuring the Safety of Marketed Medical Devices* 22 (2006), *available at* http://www.fda.gov/cdrh/postmarket/mdpi-report.pdf.

When adverse events are reported, there are "no specific rules" requiring further investigation, and "judgments about appropriate FDA responses have a considerable subjective component." *Safe Medical Devices for Children* at 125. Resource constraints "limit the agency's ability to investigate [adverse-event] reports that do not involve deaths and other high-profile events." *Id.* at 125-26. Manufacturers may report information in annual reports that are limited to a "summary and bibliography" of

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[7] Amendments to the MDA, which incorporate limited postmarket surveillance, indicate further congressional recognition that PMA provides only a screening function. As the Institute of Medicine reported:

> The statutory provisions for postmarket studies reflect Congressional awareness that the data and assessments associated with the approval or clearance of a complex medical device may leave meaningful unanswered questions about uncommon adverse events, effects in groups not studied . . . and long-term effects. To the extent that FDA encourages and accepts smaller, faster, and otherwise more limited studies to promote earlier consideration of a device for approval and reduce burdens on sponsors, more questions may remain for the postmarket period.

Institute of Medicine, *Safe Medical Devices for Children* 184 (Marilyn J. Field & Hugh Tilson eds., 2005).

information not included in the PMA application. 21 C.F.R. § 814.84(b)(2). Even where manufacturers must provide postmarket data pursuant to their PMA approval, the Institute of Medicine discovered a "disappointing picture of the agency's performance in monitoring study commitments for medical devices." *Safe Medical Devices for Children* at 192.

Even after discovering that a device for which it provided premarket approval is defective, the FDA has few tools at its disposal. Nearly all device recalls are voluntarily undertaken and directed by the manufacturer, rather than by the FDA.[8] Nor can the FDA order the recall of all PMA devices that no longer meet the threshold standards of safety and efficacy; it can do so only when it finds there is a reasonable probability that the device would cause "serious, adverse health consequences or death." 21 C.F.R. § 810.10(a). Even that limited authority is exercised rarely.

**2.** The FDA also has limited authority to regulate design, manufacturing, and labeling changes to a device after it receives premarket approval. First, a manufacturer can make any change after premarket approval without further FDA review if that change, in the manufacturer's judgment, does not "affect[] safety or effectiveness." 21 U.S.C. § 360e(d)(6)(A)(i). FDA regulations explain that "the burden of determining whether a [PMA] supplement is required is primarily on the PMA holder." 21 C.F.R. § 814.39(a).

Second, after premarket approval, the device maker can make manufacturing changes to a device with minimal FDA oversight. It need only give notice to the FDA that describes the change, "summarizes" any supporting data or other information, and informs the FDA that the manufacturer is adhering to good manufacturing practices. *See* 21 U.S.C. § 360e(d)(6)(A)(ii). Unless the FDA

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[8] *See* FDA, *Learn About Medical Device Recalls*, http://www.fda.gov/cdrh/recalls/learn.html (last visited Aug. 23, 2007).

objects, within 30 days of the notice, no FDA approval is needed for the manufacturing change to the device.

Finally, even for device changes, which require FDA approval when the manufacturer admits the change affects safety or effectiveness, the FDA provides a streamlined version of the original PMA process called a supplemental PMA. *See id.* § 360e(d)(6)(A)(i); *see also* 21 C.F.R. § 814.39(c) ("the information required in [a supplemental PMA application] is limited to that needed to support the change"). Certain labeling changes or changes to "quality controls or manufacturing process" can be implemented while a PMA supplemental application is still pending, so long as the manufacturer believes the changes enhance safety. 21 C.F.R. § 814.39(d). The FDA reviews a supplemental PMA application—like that submitted and approved for the Evergreen Balloon Catheter, *see* Pet. App. 3a-4a—in approximately 60 percent less time than it devotes to an original PMA. *See* Center for Devices and Radiological Health, *Office of Device Evaluation and Office of InVitro Diagnostic Device Evaluation and Safety Annual Report* (2003), *available at* http://www.fda.gov/cdrh/annual/fy2003/ode/2003.pdf.

The availability of multiple methods through which device manufacturers can update and redesign products, manufacturing methods, and device labeling forecloses a claim that PMA approval imposes any requirement upon the device. *Cf. Bates*, 544 U.S. at 451 ("Unlike the cigarette labeling law at issue in *Cipollone* [*v. Liggett Group, Inc.*, 505 U.S. 504 (1992)], which prescribed certain immutable warning statements, FIFRA contemplates that pesticide labels will evolve over time, as manufacturers gain more information about their products' performance in diverse settings."). The MDA provides ample opportunities for device makers to adopt different designs, manufacturing methods, and labeling, with limited and streamlined regulatory oversight. PMA approval imposes no immutable requirements upon a device manufacturer.

## II. THE TORT SYSTEM PROVIDES REMEDIES AND INCENTIVES NECESSARY TO PROTECT THE PUBLIC AND TO COMPENSATE PATIENTS INJURED BY DEFECTIVE MEDICAL DEVICES THAT RECEIVED PREMARKET APPROVAL

Unlike the constrained premarket approval process, the state tort system protects consumers from dangerous medical devices. Through litigation, the public gains information about dangerous devices and wider problems within the medical device industry and with the FDA's regulatory regime. Furthermore, unlike the FDA, litigation compensates those who are injured by defective medical devices. Recent cases involving products that obtained premarket approval, such as defibrillators, heart valves, and hip implants, have highlighted defects that seriously injured consumers and demonstrated the value of litigation in informing the public and compensating victims.

### A. By Uncovering Information About Defective Medical Devices, Litigation Spurs Improvements In The Medical Device Industry And The FDA

1. As this Court recognized in *Bates*, "tort suits can serve as a catalyst" to improve industry and federal regulatory practices, by "'aid[ing] in the exposure of new dangers'" and addressing their consequences. 544 U.S. at 451 (quoting *Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1541-42 (D.C. Cir. 1984)). When "devices that do more harm than good . . . reach consumers," litigation can "help uncover previously unavailable data on adverse effects, questionable practices by manufacturers, and flaws in . . . regulatory systems." David C. Vladeck, *Preemption and Regulatory Failure*, 33 Pepp. L. Rev. 95, 122, 129 (2005); Aaron S. Kesselheim & Jerry Avorn, *The Role of Litigation in Defining Drug Risks*, 297 J. Am. Med. Ass'n 308, 308 (2007). Thus, by "dropping inflated information costs and sparking public understanding and debate," litigation

"jump-starts the market and political process," leading to better regulatory oversight and improved compliance with regulations. Wendy Wagner, *When All Else Fails: Regulating Risky Products Through Tort Litigation*, 95 Geo. L.J. 693, 710 (2007).

In line with this Nation's long tradition of favoring "private law enforcement" over bureaucratic regulation, litigants have broad powers to obtain information from device manufacturers, while, by statute, the FDA has relatively few discovery tools, obtaining principally what manufacturers choose to reveal (*see supra* Part IA). *See, e.g.*, Paul D. Carrington, *Recent Efforts to Change Discovery Rules: Advice for Draftsmen of Rules for State Courts*, 9 Kan. J.L. & Pub. Pol'y 456, 457-58 (2000) ("Private litigants in America thus do, and do more effectively, much of what is in other industrial states done by . . . an administrative bureaucracy."). Unlike the FDA, "litigants can demand all documents and information that ha[ve] bearing on a product's health risks," creating a much "more complete picture of the manufacturers' information on product risks than narrowly drafted self-reporting requirements do." Wagner, 95 Geo. L.J. at 700. These broad discovery and document production powers give litigation a "singular role . . . in educating the public about unscrupulous and socially dangerous business practices detrimental to the public health." Robert L. Rabin, *Keynote Paper: Reassessing Regulatory Compliance*, 88 Geo. L.J. 2049, 2068 (2000). By "identifying and substantiating problems" with particular medical devices, litigation alerts the public to potential dangers. Catherine T. Struve, *The FDA and the Tort System: Postmarketing Surveillance, Compensation, and the Role of Litigation*, 5 Yale J. Health Pol'y, L. & Ethics 587, 606 (2005).

The public is also "substantially dependent on the tort system" to uncover problems within the medical device industry as a whole and with the FDA itself. Rabin, 88 Geo. L.J. at 2069. In addition to highlighting problematic industry behavior, litigation has "helped identify regulatory policies that can keep unsafe [products] on the

market" and has "exposed important limitations in the FDA information collection and dissemination procedures." Kesselheim & Avorn, 297 J. Am. Med. Ass'n at 310. For instance, the Guidant defibrillator litigation exposed the deficiencies in disclosure practices in the heart device industry, and the Sulzer hip implant litigation revealed that the FDA was failing to inspect medical device factories as frequently as the MDA requires. *See In re Guidant Corp. Implantable Defibrillators Prod. Liab. Litig.*, MDL No. 05-1708 (DWF/AJB), Civil No. 06-25 (DWF/AJB), 2007 WL 1725289 (D. Minn. June 12, 2007); *In re Sulzer Hip Prosthesis & Knee Prosthesis Liab. Litig.*, 455 F. Supp. 2d 709, 712 (N.D. Ohio 2006).

By publicizing such problems, litigation spurs the "industry to improve safety, the FDA to implement more stringent controls, individuals to improve health habits, and health care providers to improve communications with patients." Elizabeth A. Weeks, *Beyond Compensation: Using Torts to Promote Public Health*, 10 J. Health Care L. & Pol'y 27, 58 (2007). Just as the Dalkon Shield litigation spurred the enactment of the MDA itself, recent litigation involving defective medical devices with premarket approval has led the medical device industry to improve its disclosure practices and safety standards, and has drawn public attention to constraints on the FDA's effectiveness. *See* Kesselheim & Avorn, 297 J. Am. Med. Ass'n at 310 (crediting the tort system with "spurring change in regulatory [and] corporate procedures, as well as extending knowledge about . . . risks by adding to the evidence available for evaluation by physicians, patients, and regulators"); *see also* Wagner, 95 Geo. L.J. at 705.

In addition to alerting the public to these dangerous devices, litigation deters misconduct by manufacturers and encourages compliance with FDA standards. The FDA's limited ability to monitor products on the market sometimes tempts manufacturers to forgo monitoring their own products or to hide problems when they discover them. *See, e.g., In re Guidant*, 2007 WL 1725289; *In re Medtronic, Inc. Implantable Defibrillators Litig.*, 465

F. Supp. 2d 886, 889 (D. Minn. 2006). As this Court recognized in *Bates*, "[t]he long history of tort litigation . . . emphasizes the importance of providing an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items." 544 U.S. at 449-50. Because "failure to comply with FDA regulations can be very damaging to the liability case of a defendant," the threat of "liability considerably strengthens company incentives to comply with FDA regulations," thereby "confer[ring] substantial safety benefits" on the public. Steven Garber, *Product Liability and the Economics of Pharmaceuticals and Medical Devices* 125 (1993); *see also Bates*, 544 U.S. at 451 ("[p]rivate remedies that enforce federal . . . requirements would seem to aid, rather than hinder, the functioning" of federal regulations).

Removing this incentive would irrationally reward misconduct by immunizing device manufacturers from tort suits when they gained or kept their premarket approval by withholding information about defects from the FDA. *See, e.g., In re St. Jude Med., Inc. Silzone Heart Valves Prod. Liab. Litig.*, No. MDL 01-1397 JRTFLN, 2004 WL 45503, at *11 n.4 (D. Minn. Jan. 5, 2004) (immunizing manufacturers that "wrongfully withhold data from the FDA . . . cannot be what Congress had in mind when it enacted the MDA because, in its judgment, medical device manufacturers needed to be more strictly regulated"); *Lohr*, 518 U.S. at 487 (Stevens, J., plurality) (removing tort liability would have the "perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation in order 'to provide for the safety and effectiveness of medical devices intended for human use'") (quoting 90 Stat. 539 (preamble to MDA)).

Even when manufacturers comply with FDA regulations and act swiftly to address problems, defective medical devices can still seriously injure patients, who depend on the tort system to provide them with information about the risks they face and compensation for the harms they suffer. *See, e.g.*, Robert Cohen & J. Scott Orr, *A Glitch*

*Can Kill, But Pacemaker Users Will Take That Chance*, Star-Ledger (Newark, N.J.), Aug. 12, 2002, at 7 (describing how a defect in Telectronics' pacemaker led to at least 18 deaths, 30 injuries, and thousands of replacement surgeries despite the company's swift and thorough response to the problem); Price Colman, *Telectronics Defends Efforts With Defective Wire*, Rocky Mountain News, Mar. 17, 1995, at 49A.

**2.** The Guidant defibrillator litigation demonstrates how litigation can reveal problems and encourage improvements in the medical device industry. Guidant, a major medical device manufacturer, obtained premarket approval for what turned out to be a seriously defective heart device. In 2000, the FDA granted premarket approval to Guidant's Prizm 2 defibrillator, a device meant to restore regular heart rhythms by delivering shocks when needed. *See* Ben Harder, *Heart Device Recall: For Patients with Suspect Models, Tough Choices*, Wash. Post, June 28, 2005, at F1. In 2002, Guidant discovered that the device had two design flaws—an ineffective insulating material and inadequate wire spacing—that gave it a tendency to short-circuit and fail. *See In re Guidant*, 2007 WL 1725289, at *2. Rather than instituting a recall, Guidant designed its newer models to address the problem, without informing the FDA. *See id.* Meanwhile, it continued to sell the older models, which it knew to be flawed, "after it had fixed the problem in newer versions." Barry Meier, *F.D.A. Expanding Inquiry into Heart-Device Company*, N.Y. Times, Aug. 25, 2005, at C3.

Guidant successfully hid its knowledge of the defect for three years. Not until 2005, when a defective Guidant defibrillator caused the highly publicized death of a college student, did Guidant inform physicians and the FDA of the design flaw. The defect was responsible for at least six other deaths. *See In re Guidant*, 2007 WL 1725289, at *3; William H. Maisel, *Safety Issues Involving Medical Devices; Implications of Recent Implantable Cardioverter-Defibrillator Malfunctions*, 294 J. Am. Med. Ass'n 955, 955 (2005). A month after the publicity began, Guidant

met with the FDA and agreed to a recall. But, by that point, the faulty devices had been implanted in about 24,000 people. *See In re Guidant*, 2007 WL 1725289, at *3; Jon Kamp, *Guidant Discloses Lawsuit Tally, Says Many More Possible*, Market Watch, Feb. 22, 2006; Marc Kaufman, *More Heart Devices Malfunction; As Sophistication Has Grown, So Have Failures, FDA Reports*, Wash. Post, Sept. 17, 2005, at A7. During litigation over Guidant's conduct, documents revealed that company executives had debated warning the public about the defects earlier and had even drafted a warning letter to doctors. But the letter was not sent, and the company allowed doctors to continue implanting patients with FDA-approved devices it knew to be dangerously flawed. *See* Mark Jewell, *Guidant's Warning Letter on Defibrillators Never Sent*, Assoc. Press, Aug. 6, 2006; Barry Meier, *Inquiry Arranged by Guidant May Aid Lawsuits and Critics*, N.Y. Times, Mar. 22, 2006, at C4; Barry Meier, *Guidant Debated Device Peril*, N.Y. Times, Jan. 20, 2006, at C1.

Litigation brought Guidant's misconduct to the public's attention and encouraged improved disclosure of problems in the heart-device industry. Under pressure from the litigation, Guidant appointed an outside panel of doctors to review its disclosure practices. The panel concluded that "engineers . . . were deciding medical issues without hearing from doctors" and that Guidant failed to provide doctors "with detailed data on defibrillator failure," so that the information "had never been communicated to patients." Meier, *Inquiry Arranged by Guidant*.

These revelations led physicians and patients' groups to call for reforms to the medical device industry, including "greater transparency in post-market surveillance," better "analysis and reporting of device performance and malfunction information," and more cooperation between doctors, the FDA, and device manufacturers. Mark Carlson et al., *Recommendations from the Heart Rhythm Society Task Force on Device Performance Policies and Guidelines* 1251 (2006). The criticisms led two other major heart device manufacturers, Medtronic and St. Jude, as well as

Guidant, to "heighten their scrutiny of device safety and reliability" by directly notifying patients of problems and allowing greater outside review of company safety data. Barry Meier, *Heart Device Makers Plan Enhanced Safety Reviews*, N.Y. Times, May 16, 2006, at C3. The Guidant litigation also spurred physicians to create an online database tracking defibrillator problems, so that they would no longer have to rely solely on information from device manufacturers, and patients would be able "to check on the safety and performance records" of their heart devices. Jeff Swiatek, *Doctors Seek Device-Flaw Database; Guidant's Belated Revelation of Defect in its Prizm 2 Defibrillator Spurs Call for Changes*, Indianapolis Star, May 31, 2005, at 1A.

**3.** The Silzone heart valve litigation shows how litigation can identify dangerously defective products that have received premarket approval and encourage the manufacturer to address the problem quickly, protecting patients. The Silzone heart valve gained premarket approval despite little proof of its safety or effectiveness. Artificial heart valves are implanted to replace patients' damaged or diseased valves. St. Jude developed the Silzone heart valve, featuring a silver coating, in the hope that silver's "anti-microbial properties" would help combat infections. *In re St. Jude*, 2004 WL 45503, at *1. The FDA gave the Silzone valve supplemental premarket approval in 1998, even though the silver-coated valve had not undergone clinical trials and had been tested in only "a small study of sheep and an 'observational study' of 20 patients for two months." Cohen & Orr, *Often the Patient Is the Last to Know*.

When the device proved to be dangerously defective, the prospect of litigation eventually encouraged the company to remove the product from the market, while the FDA took little action. After St. Jude began selling the Silzone valves to patients, clinical tests revealed that the silver coating not only did not prevent infections, but also caused the valves to leak. *See id.*; *In re St. Jude*, 2004 WL 45503, at *1. According to St. Jude, the company

"followed all the [FDA's] rules and procedures, and . . . fully informed the FDA of [its] analysis." Cohen & Orr, *Often the Patient Is the Last to Know* (internal quotation marks omitted). The then-head of the FDA's Center for Devices and Radiological Health agreed that the Silzone valve was "one of those [problems] you just don't detect until you have a larger experience." *Id.* (internal quotation marks omitted). Nonetheless, the defect was likely responsible for at least one death, a woman who died of heart failure a month after her third surgery, to replace her second defective Silzone valve, "her heart never having fully recovered from the strain of the three operations." *Id.* And at least 36,000 defective Silzone valves had been implanted in patients before St. Jude, in the face of lawsuits, issued a voluntary recall. *See id.* In response to St. Jude's voluntary recall, the FDA, which had taken no previous action, "informed St. Jude that its actions would be classified as a 'recall'" and that it considered the valves to be "defective." *In re St. Jude*, 2004 WL 45503, at *2.

**4.** Finally, the Medtronic defibrillator litigation demonstrates that, when device manufacturers obtain premarket approval by concealing information from the FDA, litigation helps reveal and punish their misconduct, encouraging increased compliance with FDA standards. In 2000, Medtronic redesigned the battery for its defibrillators and received supplemental premarket approval from the FDA for the changes. *See In re Medtronic*, 465 F. Supp. 2d at 889. Early in 2003, Medtronic discovered that the battery had a defect, which sometimes caused it to short-circuit. *See id.* When a battery short-circuited, it would deplete "within a few hours to a few days, after which there is a complete loss of device function." *Id.* at 890. Instead of informing doctors, patients, or the FDA of this defect, Medtronic began redesigning the battery, meanwhile obtaining FDA premarket approval for three additional defibrillator models containing the battery Medtronic knew to be defective. *See id.* at 889.

Several months after it discovered the defect, Medtronic received supplemental premarket approval for design changes to the defective battery, finally informing the FDA that the older model was prone to short-circuit. *See id.* But neither the FDA nor Medtronic instituted a recall of the faulty models or informed patients or physicians of the problem, and Medtronic continued to sell defibrillator models with the defective battery. *See id.* at 889-90. As evidence mounted that batteries in patients' defibrillators had failed, raising the threat of lawsuits, Medtronic finally warned doctors about the defect—more than two years after the company had discovered it. *See id.* at 890. Medtronic then initiated a recall of more than 100,000 defective defibrillators. *See* FDA, *Enforcement Report*, http://www.fda.gov/bbs/topics/enforce/2005/ENF00891.html (Mar. 16, 2005).

### B. Litigation Compensates Victims Of Defective Medical Devices

1. A critical function of litigation is to make whole the victims of others' misconduct. *See* Mark Geistfeld, *Negligence, Compensation, and the Coherence of Tort Law*, 91 Geo. L.J. 585, 597-602 (2003). As this Court noted in *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002), state tort actions, "unlike most administrative and legislative regulations[,] necessarily perform an important remedial role in compensating accident victims." *Id.* at 64; *see also Cipollone*, 505 U.S. at 537 (Blackmun, J., concurring in the judgment in part and dissenting in part) (recognizing that "tort law has an entirely separate function—compensating victims—that sets it apart from direct forms of regulation"). When defective medical devices reach the market, whether or not the manufacturer complied with FDA regulations, patients are often seriously injured, both physically and financially. Compensation helps shield patients from the crushing financial burdens caused by defective devices. Those injured by defective devices are often left temporarily unable to work or to enjoy normal lives; some never fully recover. And, in addition to suffering physical injury, pain, and anxiety,

patients often must undergo costly and dangerous surgeries to replace the defective devices, devices that themselves may be extremely expensive. *See, e.g.*, J. Scott Orr & Robert Cohen, *Messy Plant Made Faulty Hip Joints; Late Federal Inspections, Denial Blamed in Class-action Lawsuit*, Times-Picayune, Aug. 13, 2002, at 1.

Tort law provides the only relief for patients injured by defective medical devices. The MDA contains no damages remedy; it cannot and was not intended to compensate victims of defective medical devices.[9] Congress passed the MDA to protect consumers from dangerous medical devices. *See* Pub. L. No. 94-295, 90 Stat. 539 (preamble); *see also* H.R. Conf. Rep. No. 94-1090, at 1 (1976), *reprinted in* 1976 U.S.C.C.A.N. 1103, 1103; Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 922 n.126 (1994). Congress could not have intended the same law to strip all remedies from consumers when that protection fails. *See* Porter, 52 Food & Drug L.J. at 9 ("Given the harsh implications of foreclosing all judicial recourse for consumers injured by defective devices, FDA does not believe that Congress intended to effect so sweeping a change without even a comment."); *see also Cipollone*, 505 U.S. at 541 (Blackmun, J., concurring in the judgment in part and dissenting in part) (noting that "[t]he Court in the past has hesitated to find pre-emption where federal law provides no comparable remedy"); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984) ("Congress would [not], without comment, remove all means of judicial recourse for those injured by illegal conduct").

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[9] The MDA has a limited provision, apparently never used, allowing the FDA to compel refunds for defective devices that present "an unreasonable risk of substantial harm" and were not "properly designed or manufactured with reference to the state of the art." 21 U.S.C. § 360h(b)(1). This provision does not provide a substitute for compensatory damages. It would have allowed, for instance, relatives of a woman who died of toxic shock syndrome caused by a defective Playtex tampon to receive only the cost of the tampon. *See O'Gilvie v. International Playtex, Inc.*, 821 F.2d 1438 (10th Cir. 1987).

It is particularly implausible that Congress intended to leave uncompensated patients injured by defective devices that received premarket approval, because those devices often present the greatest dangers. *See* 21 U.S.C. § 360c(a)(1)(C) (Class III medical devices may present "a potential unreasonable risk of illness or injury"). Instead of creating a regulatory mechanism for compensating victims of defective medical devices, Congress left this important function to the traditional forum—the state courts. *See* Rabin, 88 Geo. L.J. at 2068, 2076 ("[R]egulatory agencies are not designed to do 'double duty' in the sense that tort law does: that is, compensating as well as creating incentives to safety.").

**2.** The Sulzer hip and knee implant litigation demonstrates the need for tort law to compensate patients whose lives are disrupted by the misconduct of device manufacturers. Litigation compensated patients who were injured by a serious manufacturing defect in Sulzer's artificial joints, including covering the cost of replacement surgeries and providing a fund for patients who had suffered further damages.

Sulzer's artificial hips and knees were designed to replace diseased joints, increasing mobility and relieving pain. Although the FDA granted the artificial joints premarket approval after an assertedly "rigorous review of the design, manufacturing methods, quality control procedures, clinical investigations, and labeling and marketing of the medical device," a manufacturing defect kept the implants from bonding properly with patients' bones. *In re Sulzer*, 455 F. Supp. 2d at 712; Orr & Cohen, *Messy Plant Made Faulty Hip Joints*. Sulzer admitted in depositions that the defect resulted from unsanitary conditions in its factory. Lubricants "leaked from machinery" left a residue on the artificial joints, which Sulzer failed to discover because it never tested the devices "for oil or other contaminants." Orr & Cohen, *Messy Plant Made Faulty Hip Joints*. The FDA had not recently inspected the factory. Although federal law requires it to inspect plants every two years, "the FDA admits that manufacturers'

plants are inspected by the agency only every five years." *Id.*

For six months, Sulzer hid its knowledge of the defect from the FDA and the public. Doctors began reporting these problems to Sulzer in June 2000. But, instead of informing the FDA or instituting a recall, Sulzer assigned "marketing and sales officials" to conduct an internal investigation. Concerned about diminishing the company's record sales of the defective products, the officials "tried to foist blame for the failed components on others," including doctors and other manufacturers. *Id.*

In December 2000, Sulzer finally informed the FDA and instituted a recall of approximately 40,000 defective hip implants. By that point, "about 26,000 had already been implanted in patients." *In re Sulzer Hip Prosthesis & Knee Prosthesis Liab. Litig.*, 268 F. Supp. 2d 907, 911 (N.D. Ohio 2003). With the FDA overseeing the recall, Sulzer "took some of the unimplanted recalled shells, cleaned them to remove the problem residue and sent them out to be implanted by orthopedists into patients." Victoria Colliver, *Surgical Manufacturer Under Fire; 'Recycled' Hip Implants Spell More Suffering; Some Defective Devices Replaced with Ones Previously Recalled*, S.F. Chron., June 2, 2002, at A3. About 6,000 of these reprocessed parts were implanted. *See id.* Soon, these "reprocessed" implants also began to fail, particularly in patients whose health had been compromised by previous defective Sulzer implants. *Id.*

The defective hips caused symptoms, according to Sulzer, of "severe groin pain and inability to bear weight on your leg." *In re Sulzer*, 268 F. Supp. 2d at 912. As one patient described his experience with a defective Sulzer hip implant, "it was pretty painful. After a while, I could walk, but it still hurt. I'd walk maybe 10 or 15 steps, and it'd catch. I'd almost go down—not quite, but close." Orr & Cohen, *Messy Plant Made Faulty Hip Joints*. Other patients lost the ability to walk without crutches. *See id.* Many needed further surgery to replace the defective

implants. Some, who received defective "reprocessed" hips to replace their first defective implants, required multiple surgeries; one woman needed five hip replacement surgeries to replace defective Sulzer implants. To their dismay, patients had no choice but to continue using Sulzer components, because the replacements needed to fit the rest of their artificial hips. *See Five Implants Later, Local Woman's Hip Still Not Right: She Says the Defective Hip Implant Caused Complications that Linger*, Grand Rapid Press, Aug. 25, 2002, at C1; Orr & Cohen, *Messy Plant Made Faulty Hip Joints*. Other patients, "medically ineligible for revision surgery," must live permanently with the pain their defective implants cause. *In re Sulzer*, 268 F. Supp. 2d at 912.

Litigation provided compensation to patients who suffered from Sulzer's misconduct. A settlement provided compensation for patients who were harmed by defective Sulzer implants, including $206,000 for each surgery a patient needed to replace a defective implant, and a $100 million fund for patients suffering extraordinary damages. *See Five Implants Later*. The litigation also convinced the company to change its manufacturing practices, including instituting "a new standard for cleanliness of products before they are sent to market." Orr & Cohen, *Messy Plant Made Faulty Hip Joints*.

## CONCLUSION

The court of appeals' judgment should be reversed.

Respectfully submitted,

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August 27, 2007

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No. 06-179

IN THE

# Supreme Court of the United States

DONNA S. RIEGEL, INDIVIDUALLY AND AS ADMINISTRATOR OF THE ESTATE OF CHARLES R. RIEGEL,

*Petitioner,*

v.

MEDTRONIC, INC.,

*Respondent.*

**On Writ of Certiorari to the United States Court of Appeals for the Second Circuit**

## BRIEF OF THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION (ADVAMED), DRI, MEDMARC, AND THE MEDICAL DEVICE MANUFACTURERS ASSOCIATION (MDMA) AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT


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TABLE OF CONTENTS


| | Page |
|---|---|
| TABLE OF AUTHORITIES | ii |
| INTERESTS OF *AMICI CURIAE* | 1 |
| SUMMARY OF ARGUMENT | 4 |
| ARGUMENT | 6 |
| I. ENHANCED STATE-LAW LIABILITY WOULD INTERFERE WITH FDA'S EXTENSIVE PRE- AND POST-MARKETING OVERSIGHT OF MEDICAL DEVICES, NOT FILL A REGULATORY "GAP" | 6 |
| A. FDA Exercises Substantial Pre-Marketing Oversight Of Medical Devices | 7 |
| B. FDA Exercises Substantial Post-Marketing Oversight Of Medical Devices | 11 |
| II. EXTENDING STATE-LAW LIABILITY WOULD UNDERMINE THE BALANCE OF PUBLIC HEALTH OBJECTIVES REFLECTED IN THE MDA | 16 |
| A. State Tort Liability Stifles Innovation Of Important And Life-Saving Medical Devices | 19 |
| B. State Tort Liability Threatens The Availability Of Significant Medical Treatments | 23 |
| C. State Tort Liability Increases Price And Undermines The Affordability Of Medical Treatments | 26 |
| D. State Tort Liability Encourages Defensive Labeling And Overwarning That Undermine Rational Prescribing By Physicians | 27 |
| CONCLUSION | 30 |

## TABLE OF AUTHORITIES

CASES — Page

*Brooks* v. *Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001) ..... 7
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*Martin* v. *Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001) ..... 7
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STATUTES AND REGULATIONS

Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 451 ..... 18
21 U.S.C. §§ 301 *et seq* ..... 5
§ 332 ..... 13
§ 333 ..... 13
§ 360c ..... 8, 10, 16, 19, 20
§§ 360c *et seq* ..... 5
§ 360d(c)(1) ..... 10

TABLE OF AUTHORITIES—continued


| | Page |
|---|---|
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| § 360h | 11, 12 |
| § 360i | 11, 12 |
| § 360j | 7, 11, 12, 17 |
| § 360k(a) | 17 |
| § 393(b)(1) | 18 |
| 21 C.F.R. § 7.3(g)-(h) | 12 |
| pt. 14 | 10 |
| §§ 56.101-56.124 | 8 |
| § 803.30 | 13 |
| § 803.50 | 13 |
| §§ 812.1-812.150 | 7 |
| § 812.30 | 8 |
| § 812.35(b) | 8 |
| §§ 812.40-812.47 | 8 |
| §§ 812.60-812.66 | 8 |
| § 812.150 | 8 |
| § 814.20 | 8 |
| § 814.39 | 11 |
| § 814.42 | 10 |
| § 814.44 | 10, 11 |
| § 814.45 | 11 |
| § 814.46 | 13 |
| § 814.80 | 11 |
| § 814.82 | 11 |
| § 814.84 | 11 |
| § 860.7 | 16 |
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Page

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## INTERESTS OF *AMICI CURIAE*[1]

*Amici*, whose members are active participants in the medical device regulatory, insurance and litigation process, are uniquely situated to alert the Court to two practical issues of significance to its decision here.

First, notwithstanding petitioner and her *amici*'s view that current federal oversight is lean and in need of all-encompassing state-law augmentation, in actuality—as *amici* here are well-aware and illustrate in detail below—the United States Food and Drug Administration ("FDA") comprehensively regulates medical devices, both before and after their launch on the United States market through the Premarket Approval ("PMA") process.

Second, *amici* are well-acquainted with numerous harmful effects of state-law liability risks in this sensitive context, in which Congress has charged an expert federal agency, FDA, with striking a careful balance of public health objectives. These harmful effects include: (i) forgoing innovation, discouraging device development, and exacerbating a growing "pipeline problem"; (ii) decreasing the availability of potentially beneficial medical treatments in the United States, particularly those relating to women's health; (iii) increasing medical costs; and (iv) encouraging "defensive labeling" that interferes with rational prescribing decisions by physicians.

*The Advanced Medical Technology Association ("AdvaMed")*, formerly known as the Health Industry Manufacturers Association, is the largest medical technology

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[1] Petitioner and respondent have consented to the filing of this *amicus* brief in letters on file with the Clerk's office. Pursuant to Rule 37.6, *amici* state that no counsel for a party authored any part of this brief, and no person or entity other than *amici* and their counsel made a monetary contribution to its preparation or submission. This brief is filed in compliance with the Court's May 2, 2005 rules. *See* Sup. Ct. R. 48.3 (2007).

association in the world. It represents more than 1,200 medical device, diagnostic, and health information system manufacturers. AdvaMed's members manufacture 90 percent of the $75 billion of health care technology purchased annually in the United States and more than 50 percent of the $175 billion purchased around the world annually.

AdvaMed's members are innovators of technologies that save lives and increase the quality of life for hundreds of thousands of patients every year. For example, technological breakthroughs such as coronary stents, implantable defibrillators, and minimally invasive bypass surgery have helped reduce the death rate from heart disease by 40 percent since 1980. AdvaMed's members spend an enormous amount of money—roughly $9 billion annually—on the research and development of these innovations. On a percentage of sales basis, this investment constitutes more than four times the average spent on research and development by non-pharmaceutical manufacturers in other industries.

One of the inevitable consequences of innovation in health care technology is that a small percentage of patients suffer injuries that they allege were caused by these highly specialized products. AdvaMed and its members therefore have a significant interest in the outcome of this litigation. Nearly all of AdvaMed's members do now or will in the future face the prospect of tort litigation concerning the medical devices they manufacture, and related costs in the form of self-insurance or insurance premiums to cover the potential risks of alleged device-related injury.

*DRI* is an international organization that includes more than 22,000 attorneys involved in the defense of civil litigation. DRI is committed to enhancing the skills, effectiveness, and professionalism of defense attorneys. Because of this commitment, DRI seeks to address issues germane to defense attorneys and the civil justice system, to promote the role of the defense attorney, and to improve the civil justice system. DRI has long been a voice in the ongoing effort to make the

civil justice system more fair, efficient, and—where national issues are involved—consistent. To promote these objectives, DRI participates as *amicus curiae* in cases that raise issues of importance to its membership and to the judicial system.

Here, to extend unbounded state tort liability to companies that have successfully brought to market the most cutting-edge medical devices pursuant to the PMA process, as petitioner urges, would threaten the efficient and fair administration of justice. Allowing states to serve as secondary regulatory bodies able to impose different or additional requirements on device manufacturers despite the express preemption provision implicated here would override Congress's intentions with respect to the PMA process and obstruct FDA from fulfilling its regulatory charge. Not only would device manufacturers be subjected to costly and uncertain litigation nationwide, but the overall economy and public health would suffer as a result of the decreased innovation triggered by the threat of liability.

The issues in this case are, accordingly, of substantial concern to DRI. Because DRI's members have first-hand experience with medical device litigation and FDA's regulatory role, DRI is well-suited to address the grave consequences of the unpredictable patchwork of state liability that petitioner's position would create.

*Medmarc Insurance Group (Medmarc)* is a specialty insurer, owned by the life science industry, which provides product liability coverage for medical device and life science manufacturers. Owned and controlled by its member policyholders in the life science industry, Medmarc was founded in 1979 by that industry in response to volatile conditions in the commercial insurance market for product liability protection. Medmarc's membership includes approximately 700 manufacturers and distributors of medical devices, biotech, generic pharmaceutical, and diagnostic products.

*The Medical Device Manufacturers Association (MDMA)* is a national trade association representing innovative and entrepreneurial medical device designers and manufacturers. Its membership includes over 150 makers of medical devices, diagnostic products, and health care information systems. MDMA seeks to improve the quality of patient care by encouraging the development of new medical technology and fostering the availability of innovative products in the marketplace.

## SUMMARY OF ARGUMENT

*Amici* will not repeat the legal arguments that are well developed by respondent and other *amici*. Instead, *amici* focus the Court's attention on two key issues.

*First*, in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), the Court observed that the § 510(k)-clearance process described in that case was "by no means comparable" to the more "rigorous" PMA process. *Id.* at 477-79. Yet petitioner and her *amici* understate the robust, device-specific pre- and post-marketing review FDA exercises in the PMA context. If anything, this oversight has increased since *Lohr*. For example, FDA has recently further enhanced its "long history of effective medical device safety as a result of both its premarket review process and its postmarket surveillance and enforcement activities" with new initiatives to enhance efforts to "identify safety signals at any point in a product's lifecycle and take timely action." Daniel G. Schultz, M.D., Director, FDA Center for Devices and Radiological Health ("CDRH"), *Medical Device Safety, FDA's Postmarket Transformation Initiative*, 62 Food & Drug L.J. 593, 593 (2007). One such initiative is the Medical Device Safety Network or "MedSun." MedSun, which has been in effect for approximately five years, supplements FDA's existing, mandatory post-marketing surveillance mechanisms with additional "valuable data on how devices are used in the real world of clinical practice," *id.* at 594, such as identifying

"close calls" and engaging in other "proactive prevention" collaboratively with clinicians and manufacturers. MedSun, About MedSun, www.medsun.net/about2.asp.

*Second*, the state tort liability urged by petitioner and her *amici* threatens to undermine the balance of safety, effectiveness, and innovation Congress has charged FDA with calibrating and would threaten numerous harmful effects. By enacting the Medical Device Amendments ("MDA"), 21 U.S.C. §§ 360c *et seq.*, to the Federal Food, Drug and Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq.*, and creating the PMA process, Congress charged FDA with striking a sensitive balance between important, and often competing, public health objectives. On the one hand, Congress sought to ensure that cutting-edge and oftentimes high-risk medical devices would offer, in the agency's expert judgment, a reasonable assurance of safety and effectiveness based on valid scientific evidence before reaching the United States market. On the other hand, Congress focused on fostering a regulatory and legal environment that promotes device innovation that is imperative to preserving and advancing important and life-saving patient treatments.

Enhanced state-law liability poses a challenge to this balance and threatens to, among other things: (i) harm the device development and innovation that Congress and FDA have endeavored to foster; (ii) undermine the availability of medically beneficial devices already on the market; (iii) raise prices for important and life-saving medical devices; and (iv) fuel the proliferation of defensive "over-warning" that undermines rational prescribing decisions, based on risks the expert agency determines to be scientifically justified, and discourages use of beneficial therapies.

## ARGUMENT

### I. ENHANCED STATE-LAW LIABILITY WOULD INTERFERE WITH FDA'S EXTENSIVE PRE- AND POST-MARKETING OVERSIGHT OF MEDICAL DEVICES, NOT FILL A REGULATORY "GAP."

In *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), the Court held that state-law claims were not preempted by the MDA's *different* Section 510(k) "substantial equivalence" process which—unlike the comprehensive PMA process at issue here—"requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly," in an average of only 20 hours. *Id.* at 477-79 (internal quotation omitted). The *Lohr* opinion observed that "the 510(k) process is focused on *equivalence* [to another approved product], not safety" and "[a]s a result, substantial equivalence determinations provide little protection to the public." *Id.* at 493 (internal quotation omitted).

In contrast, the Court juxtaposed the "rigorous" PMA process in which FDA spends "an average of 1,200 hours on each submission." *Id.* at 477. The Court underscored that "[t]he § 510(k) notification process is by no means comparable to the PMA process," *id.* at 478-79, and

> *quite unlike* a case in which the Federal Government has weighed the competing interests relevant to the particular requirement in question, reached an unambiguous conclusion about how those competing considerations should be resolved in a particular case or set of cases, and implemented that conclusion via a specific mandate on manufacturers or producers. [*Id.* at 501 (emphasis added).]

In keeping with this analysis, nearly every Circuit to have considered the issue (including the Second Circuit below) has

concluded that most state-law claims with respect to PMA-approved medical devices are preempted.[2]

Petitioner and her *amici* seek to undermine the force of this analysis by suggesting that PMA devices actually receive little oversight by FDA. See, *e.g.*, Pet. Br. 4-6, 24-31; Br. *Amici Curiae* Am. Ass'n for Justice et al. 22-27. They then advance the position that state law can properly serve as "a complement" to the PMA process and is "congenial to" Congress's charge and FDA's regulation of PMA devices. Br. *Amicus Curiae* Consumers Union 11. Their view is mistaken.

As recognized in the *Lohr* decision, the PMA process involves robust federal regulation affecting every stage of the development and marketing of a medical device, both before and after FDA permits it to reach the United States market. If anything, this review—and the case for preemption—has become even stronger since the time of *Lohr*.

### A. FDA Exercises Substantial Pre-Marketing Oversight Of Medical Devices.

Even before the PMA process begins, manufacturers typically must satisfy extensive FDA requirements to gain a so-called Investigational Device Exemption ("IDE") to authorize clinical investigations involving human subjects. To obtain an IDE, the manufacturer must make detailed submissions to FDA regarding every aspect of the device and clinical investigation. See 21 U.S.C. § 360j(g); 21 C.F.R. §§ 812.1-812.150 (regulations applicable to IDEs). During the IDE process, FDA reviews voluminous materials and

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[2] *See, e.g.*, Pet. App. 2a; *McMullen* v. *Medtronic, Inc.*, 421 F.3d 482 (7th Cir. 2005), *cert. denied*, 547 U.S. 1003 (2006); *Cupek* v. *Medtronic, Inc.*, 405 F.3d 421 (6th Cir.), *cert. denied*, 546 U.S. 935 (2005); *Horn* v. *Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004); *Brooks* v. *Howmedica, Inc.*, 273 F.3d 785 (8th Cir. 2001) (en banc); *Martin* v. *Medtronic, Inc.*, 254 F.3d 573 (5th Cir. 2001); *but see Goodlin* v. *Medtronic, Inc.*, 167 F.3d 1367 (11th Cir. 1999).

evaluates whether "the anticipated benefits to the subjects and the importance of the knowledge to be gained" from such trials outweighs the estimated "risks to the subjects," and further ensures that the informed consent provisions are adequate, the investigation is scientifically sound, and there is no reason to believe the device will be ineffective. 21 C.F.R. § 812.30; see *Martin* v. *Telectronics Pacing Sys., Inc.*, 105 F.3d 1090, 1095-96 (6th Cir. 1997) (describing IDE process and related preemption issues). Clinical investigations generally require prior approval from an Institutional Review Board ("IRB")—an independent scientific reviewing body acting under the auspices of the National Institutes of Health. See 21 C.F.R. §§ 56.101-56.124 (IRB regulations); 45 C.F.R. §§ 46, *et seq.* (Health and Human Services regulations regarding protection of human subjects and pertaining to IRBs); see also, *e.g.*, 21 C.F.R. §§ 812.35(b), 812.40-812.47, 812.60-812.66, 812.150(a)-(b) (imposing IDE-specific IRB requirements).

Before FDA can determine that a device is safe and effective through the PMA process, 21 U.S.C. §§ 360c(a)(1)(C)(i), 360e(d)(2), it reviews exhaustive submissions. A PMA application must include: (1) full reports of all safety and efficacy investigations; (2) a full statement of the device's components, ingredients, properties, and principles of operation; (3) a complete description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing or installation of the device; (4) information demonstrating compliance with statutory performance standards; (5) samples of the device, if requested by the FDA; (6) specimens of proposed labeling; and (7) any other information FDA requires. See 21 U.S.C. § 360e(c)(1); *id.* § 360e(f)(3); 21 C.F.R. § 814.20 (requiring statements of indications for use, device description, alternative practices and procedures, marketing history, summary of studies, and study conclusions).

These submissions typically include "'thousands of pages of documentation'" to which FDA must apply its expert analysis to determine whether there is a reasonable assurance of safety and efficacy. *Horn* v. *Thoratec Corp.*, 376 F.3d 163, 172 (3d Cir. 2004) (quoting *amicus curiae* brief of the United States); see *Rattay* v. *Medtronic, Inc.*, 482 F. Supp. 2d 746, 748 (N.D.W. Va. 2007) (PMA application exceeded 1,700 pages); *Steele* v. *DePuy Orthopaedics, Inc.*, 295 F. Supp. 2d 439, 444 (D.N.J. 2003) (PMA application 2,000 pages before supplements).

During this review, FDA informs the manufacturer if there are any "major" or "minor" deficiencies that must be satisfactorily addressed before the PMA application can move forward. See generally FDA, CDRH, *Review Process* June 11, 2003), www.fda.gov/cdrh/devadvice/pma/review_process.html. For example, "[o]ne of the most important aspects of the device approval process is the development of a meaningful and accurate product label" and the agency "works closely with the manufacturer to create this label." I. Muni et al., *Challenges in Regulating Breakthrough Medical Devices*, 60 Food & Drug L.J. 137, 138 (2005). If FDA determines that the application is deficient in any respect (*e.g.*, labeling, manufacturing, design specifications), it may take a manufacturer months, if not years, to cure the deficiency. See, *e.g.*, *Horn*, 376 F.3d at 169-70 (PMA process began in 1975, PMA application submitted to FDA in 1992, and device approved in 1994); *Kemp* v. *Medtronic, Inc.*, 231 F.3d 216, 219 (6th Cir. 2000) (four years between IDE approval and PMA approval).[3]

During this process, the agency draws on its unique vantage point. Indeed, FDA "holds the only broad, cross-cutting knowledge" and "experience with the totality of other

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[3] Such back-and-forth would not be necessary, of course, if FDA determines the PMA application fully answers its questions in the first instance and no remaining issues need to be addressed.

applications," and also utilizes its knowledge of "the latest science." FDA, *Innovation or Stagnation: Challenge and Opportunity on the Critical Path to New Medical Products* 13 (Mar. 2004), *available at* www.fda.gov/oc/initiatives/criticalpath/whitepaper.html. To the extent an application does not meet FDA's standards or the agency has questions, there may need to be substantial back-and-forth between the manufacturer and agency. In *Horn*, for example, after the manufacturer submitted its PMA application to FDA it "supplemented it in the ensuing three years with a substantial amount of amendments and responses to FDA questions." *Horn*, 376 F.3d at 170.

Even after a manufacturer satisfies any deficiencies flagged by FDA, the agency generally refers the application to an independent committee of experts, which holds a public meeting to review the device and prepares a report and recommendation to FDA on whether a device is safe and effective. See 21 U.S.C. § 360e(c)(2); 21 C.F.R. pt. 14; *id.* §§ 814.42, 814.44; FDA, *Review Process*, *supra*. After the committee issues its recommendation, FDA considers that information along with the other submissions to determine whether the device's "safety and effectiveness" has been demonstrated through "valid scientific evidence." 21 C.F.R. § 860.7; FDA, *Review Process*, *supra* (recognizing that even after a committee recommendation, FDA may require additional submissions from the manufacturer).[4]

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[4] Since *Lohr*, FDA also has increased its scrutiny of a limited set of § 510(k) devices. In FDAMA, Congress augmented the § 510(k) process by allowing manufacturers an option of gaining clearance by utilizing conformance with FDA recognized standards to demonstrate safety and efficacy equivalent to a predicate device. *See* 21 U.S.C. § 360d(c)(1); *id.* § 360c(i)(1)(A)(ii); FDA, CDRH, *Recognition and Use of Consensus Standards; Final Guidance for Industry and FDA Staff* (June 20, 2001), *available at* www.fda.gov/cdrh/ost/guidance/321.html ("In the case of 510(k)s, information on conformance with recognized consensus standards may help establish the substantial equivalence" and "can be

If FDA determines that a manufacturer has provided reasonable assurance that the device is safe and effective for its intended use, the agency then issues a letter order incorporating by reference the submissions pertaining to this regulatory process and permitting the manufacturer to market the device in the United States. It does so after a manufacturer demonstrates that the manufacturing and processing methods and facilities conform to FDA requirements, and that the proposed labeling is not false or misleading. *See* 21 U.S.C. § 360e(d)(2); 21 C.F.R. § 814.45. Thereafter, as described below, the manufacturer may not alter design, labeling, or manufacturing process in any way that would affect the safety or effectiveness of the device or "is inconsistent with any conditions to approval specified in the PMA approval order for the device" without FDA approval. *Id.* § 814.80.

### B. FDA Exercises Substantial Post-Marketing Oversight Of Medical Devices.

After a PMA application is approved, FDA's comprehensive oversight continues—and has been enhanced further in recent years. See, *e.g.*, 21 C.F.R. § 814.44; FDA, *Review Process*, *supra*. For instance, the manufacturer may have to satisfy further conditions of approval for the device to remain on the market. 21 C.F.R. § 814.82(a). As noted, a manufacturer may not change the approved product design, labeling, or manufacturing process in any manner that would affect the safety or effectiveness of the device without FDA approval. *Id.* § 814.80; *id.* § 814.39 (requiring prior FDA approval for most modifications). The manufacturer is subject to audit and inspection by FDA. See 21 U.S.C. §§ 360h, 360i, 360j; 21 C.F.R. §§ 814.80, 814.82, 814.84.

FDA's oversight of safety issues continues post-marketing, as the device moves from the realm of clinical study to

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used to show that the new device is as safe and effective as the predicate in the areas covered by the standards.").

broader, real-world clinical use. As the FDA Deputy Commissioner has explained, "even for a product that is rigorously tested preapproval, some risks will become apparent only after approval, when the product is used in tens of thousands or even millions of patients in the general population." Scott Gottlieb, *Latest Trends in FDA Practice*, 878 PLI/Pat 525, 536 (2006). This can occur, for example, with respect to rare side effects. See Muni, *supra*, at 138-39.

As the American Medical Association has long recognized, FDA's "post marketing surveillance outside of formal studies constitutes a vital activity in ensuring the safety of drugs and devices." Am. Med. Ass'n, *Reporting Adverse Drug and Medical Device Events: Report of the AMA's Council on Ethical and Judicial Affairs*, 49 Food & Drug L.J. 359, 360 (1994). Of course, if Congress instead had enacted a different regulatory system that effectively "forbid marketing of a [device] until all long-term consequences and interactions are identified through formal research[, it] would impose unacceptable costs in the form of untreated or inadequately treated illness." *Id.*

FDA has a continuing role in notifying healthcare professionals (and affected individuals) of risks presented by medical devices, see 21 U.S.C. § 360h(a), requiring manufacturers to repair or replace defective devices, *id.* § 360h(b), instituting recall campaigns, *id.* § 360h(e),[5] overseeing required recordkeeping and reports of adverse reactions and injuries associated with devices, *id.* § 360i, and requiring post-market surveillance of devices, *id.* § 360j. In

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[5] FDA has different classes of "recall," most of which do not involve a product's removal from the market, and which range from addressing potentially serious issues (Class I) to simply correcting matters that "are unlikely to cause any adverse health reaction" (Class III). FDA, *FDA Recall Policies* (June 2002) *available at* www.cfsan.fda.gov/~lrd/recall2.html; *accord* FDA, CDRH, *FY 2006 Highlights* 30 (2006); *see* 21 C.F.R. § 7.3(g)-(h); Muni, *supra*, at 141 (stating there are approximately 1,000 "recalls" per year yet only 10-20 per year are designated as Class I).

addition, FDA may revoke PMA approval if it subsequently determines, *inter alia*, that a device is no longer safe and effective or that the manufacturer has not satisfied postapproval requirements. See *id.* § 360e(e); 21 C.F.R. § 814.46. Furthermore, FDA can invoke injunctive relief, seizure, criminal, and civil monetary penalty options for non-compliance. See 21 U.S.C. §§ 332, 333.

Moreover, since *Lohr* was decided, FDA has enhanced post-approval oversight. See generally Daniel G. Schultz, M.D., Director of FDA's CDRH, *Medical Device Safety: FDA's Postmarket Transformation Initiative*, 62 Food & Drug L.J. 593, 593 (2007) ("[W]e have instituted significant changes over the past few years in our approach to postmarket medical device issues."); *id.* at 595 (stating that the measures rely on "expert[ise]" in all aspects of medical device development and regulation to "manage device-related public health issues" including "comprehensive review of medical device performance through a product's lifecycle"); Muni, *supra*, at 139 (discussing enhancements since 2002).

Among other initiatives, FDA has (i) issued guidance regarding how post-approval studies are to be conducted, see, *e.g.*, FDA, *Guidance for Industry and FDA Staff - Procedures for Handling Post-Approval Studies Imposed by PMA Order* (Aug. 1, 2007); (ii) utilized Public Health Notifications and the "FDA Patient Safety News" program to disseminate information about device-related risk, see Muni, *supra*, at 141; and (iii) supplemented the existing post-marketing Medical Device Reporting ("MDR") system, 21 C.F.R. §§ 803.30, 803.50, with the Medical Device Safety Network or "MedSun." Schultz, *supra*, at 594; Muni, *supra*, at 139.

Launched in 2002, MedSun draws on active reporting from practitioners in healthcare facilities across the United States "of problems like close calls or the rejection of a device over safety concerns." MedSun; About MedSun, www.medsun.net/about2.asp. As an interactive surveillance and compliance program, when an issue is raised, "MedSun researchers

work with each facility's representatives to clarify the situation and fully understand the problem. Reports are later shared without facility identification so that clinicians can take necessary preventative actions." *Id.*

FDA has been active in responding to potential "safety signals" emitted by the reporting systems, as well as engaging in compliance and enforcement where appropriate. See Schultz, *supra*, at 593 ("over the past five years, we have seen an increase in the number of adverse event reports received"). For instance, FDA recently reported that in the last quarter of fiscal year 2006 alone its "safety analysts identified over 100 new and ongoing medical device safety issues" and "responded to over 100 consult requests related to information in the reports database." FDA, CDRH, *FY 2006 Highlights* 28 (2006); see also *id.* at 29 (discussing fiscal year 2006 actions including ordering postmarket surveillance studies, continuing ongoing surveillance, and issuing warning letters for postmarket surveillance violations). During 2006, CDRH took at least 55 enforcement actions, including four seizures and an injunction, and initiated hundreds of correction actions. *Id.* at 30.

During this process, collaboration between the agency and the manufacturer is integral to ensuring patient safety:

> [T]his cooperation between FDA and its regulated industries has been demonstrated to be the quickest and most reliable method to remove potentially dangerous products from the market. This method has been successful because it is in the interest of industry, as well as FDA, to get unsafe and defective products out of the hands of clinicians and patients as soon as possible. [Muni, *supra*, at 140.]

Furthermore, FDA has the expert perspective necessary to ensure that the correct measure of oversight is employed. See *id.* at 141 (noting that, in some cases, inspections may be

necessary whereas, in others, spot checks alone might be sufficient to cure the identified problem).

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Given FDA's continuing pre-approval scrutiny of PMA devices, see *Lohr*, 518 U.S. at 477, and the increase in post-approval oversight, the potential for state-law interference has grown since this Court last considered the MDA in *Lohr*. In this light, the case for preemption in the PMA context is even stronger than this Court previously suggested. Cf. *id.* at 478-79 (contrasting § 510(k) review with PMA).

State-law tort actions, in contrast, cannot promise the swiftness with which FDA can act; fail to account for the safety-efficacy-innovation balance both Congress and FDA have sought to strike; and lack the expert perspective central to fulfilling the multiple objectives of Congress. Expansive state tort liability not only provides a form of additional regulation, but would "regulate" in a manner completely untethered to the designs of the MDA and PMA process such that it undoes their purposes.[6] Moreover, lay juries are not institutionally well-equipped to make the kinds of nuanced risk-benefit calculations and scientific judgments Congress

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[6] Petitioner's *amici*, including the American Association for Justice and Public Justice, admit that tort liability functions as a form of regulation. Br. *Amici Curiae* Am. Ass'n for Justice et al. 18-19. Although they posit that the enhanced state-law liability they seek "promot[es] optimal deterrence," they do not (and cannot) reconcile their position with the deterrence balance already reached by FDA, which is charged by Congress with balancing considerations of safety, efficacy, and innovation. *Id.* at 18 (internal quotation omitted). To have state tort liability promote "optimal deterrence" that hinges on "minimiz[ing] the sum of accident costs" would necessarily unravel the PMA regime, which purposely allows—and encourages—devices with the greatest degree of risk to come to market under the expert agency's close oversight. In the end, petitioner and her *amici* seek to have state law second-guess and supplant the public health balance struck by Congress and the individual balancing determinations reached by FDA as to particular devices.

has charged FDA—as the expert federal agency—with making. For example, mock jury studies explain that lay jurors tend to overestimate the level of risk of low probability events, overreact to risks posed by new technology, and punish defendants for undertaking risk-benefit analyses. See Reid Hastie & W. Kip Viscusi, *What Juries Can't Do Well: The Jury's Performance As a Risk Manager*, 40 Ariz. L. Rev. 901, 909-11 (1998).[7]

## II. EXTENDING STATE-LAW LIABILITY WOULD UNDERMINE THE BALANCE OF PUBLIC HEALTH OBJECTIVES REFLECTED IN THE MDA.

The enhanced state-law liability petitioner seeks would threaten the calibrated public health balance at the heart of the MDA. On the one hand, the MDA seeks to protect patients by ensuring that medical devices are marketed in the United States only after FDA determines that they meet the requisite threshold of safety and effectiveness based on valid scientific evidence. See, *e.g.*, 21 U.S.C. §§ 360c(a)(1), 360e(d)(2); 21 C.F.R. § 860.7; FDA, FDA's Mission Statement, www.fda.gov/opacom/morechoices/mission.html (FDA's mission includes "protecting the public health by assuring the safety, efficacy, and security of . . . medical devices").

On the other hand, the MDA recognizes that device development, innovation, and availability are essential to improving public health. Indeed, Congress expressly sought to foster innovation in medical device technology and "to encourage, to the extent consistent with the protection of the public health and safety and with ethical standards, the discovery and development of useful devices intended for

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[7] *See, e.g.*, W. Kip Viscusi, *Jurors, Judges, and the Mistreatment of Risk By the Courts*, 30 J. Legal Stud. 107, 111-14 (2001) (finding mock jurors misapplied cost-benefit analyses particularly in low-probability, large-loss cases); W. Kip Viscusi, *Corporate Risk Analysis: A Reckless Act?*, 52 Stan. L. Rev. 547, 588 (2000) (jury awards and attitudes skeptical of risk-benefit analyses).

human use." 21 U.S.C. § 360j(g)(1). As the Senate Committee Report explains:

> As medicine progresses, as research makes new breakthroughs, an increasing number of sophisticated, critically important medical devices are being developed and used in the United States. These devices hold the promise of improving the health and longevity of the American people. The Committee wants to encourage their research and development. [S. Rep. No. 94-33, at 2 (1975).]

Such innovation leads to more effective, safer, and more affordable treatments. See *id.*

The express preemption provision at issue here arose in this context of balancing important public health objectives.[8] Addressing the propriety of the express preemption provision in light of the importance of device development, the House Report counseled that "if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the federal government, interstate commerce will be unduly burdened," and preemption will be necessary to ensure that "innovations in medical device technology are not stifled by unnecessary regulation." H.R. Rep. No. 94-853, at 12, 45 (1976); see *id.* at 10 (protecting the public from unsafe devices is "counterbalanced by an equally strong conviction that excessive or ill-conceived Federal device regulation would stifle progress in this field"); *id.* at 12 (stating that MDA "reflects the need to develop innovative new devices"); *Hearings on H.R. 5545, H.R. 974 & S. 510 Before the Subcomm. on Health & the Environment of the H. Comm. on Interstate & Foreign Commerce*, 94th

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[8] The express preemption provision appears at 21 U.S.C. § 360k(a). The briefs of respondent and its other *amici*, as well as the Second Circuit's decision below ably detail the application of this provision to the PMA context. We will not burden the Court by repeating that analysis here.

Cong. 201 (1975) (Statement of Rep. Fred Rooney) (urging passage of the MDA to replace the "piecemeal" and "after the fact" approach typified by then-existing judicial remedies).

In 1990, Congress reaffirmed that its goals included encouraging medical device development to flourish when it amended the MDA. See Safe Medical Devices Act of 1990, Pub. L. No. 101-629, 104 Stat. 4511 ("SMDA"). "Simply put, the [MDA] sought to avoid overregulation, thus eliminating unnecessary resource costs to industry and government, foster incentives to encourage innovation in a relatively youthful industry and, most importantly, provide the public reasonable assurances of safe and effective devices." S. Rep. No. 101-513, at 13 (1990).[9]

Following *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), Congress again sought to encourage innovation through the Food and Drug Administration Modernization Act of 1997 ("FDAMA"). There, Congress further refined FDA's mission, requiring the agency, *inter alia*, to "promote the public health by promptly and efficiently reviewing clinical research and taking appropriate action on the marketing of regulated products in a timely manner." 21 U.S.C. § 393(b)(1). Indeed, "[a] central purpose of the [FDAMA] is 'to ensure the timely availability of safe and effective new products that will benefit the public and to ensure that our Nation continues to lead the world in new product innovation and development.'" FDA, *The Least Burdensome Provisions of the FDA Modernization Act of 1997: Concepts &*

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[9] Statements by a cross-section of members of Congress echo these objectives. *See, e.g.*, 136 Cong. Rec. S15205, S15211 (daily ed. Oct. 12, 1990) (statement of Sen. Kennedy) (objectives include "encourag[ing] technological innovation"); *id.* at S12493 (daily ed. Aug. 4, 1990) (statement of Sen. Dodd) (MDA "is structured to guard against excessive governmental restrictions which might inhibit innovation in the development and advancement of biomedical products"); *id.* at S17459 (daily ed. Oct. 27, 1990) (statement of Sen. Hatch) (legislation "balance[s] the need for regulation with the benefits of innovation").

*Principles; Final Guidance for FDA & Industry* (Oct. 4, 2002) (quoting S. Rep. No. 105-43 (1997)) ("Congress'[s] goal was to streamline the regulatory process (i.e., reduce burden) to improve patient access to breakthrough technologies."), *available at* www.fda.gov/cdrh/ode/guidance/1332.html.

The state-law liability petitioner seeks to impose would trigger, or exacerbate, harmful effects contrary to these congressional purposes. These effects include discouraged innovation, diminished availability, increased costs, and defensive labeling—each of which would undermine public health.[10]

### A. State Tort Liability Stifles Innovation Of Important And Life-Saving Medical Devices.

The state tort liability for which petitioner advocates would stifle medical device innovation, thereby exacerbating an already serious "pipeline problem" in the development of important medical devices. Robust research and development is the catalyst for safer devices and new devices that may address previously untreatable or poorly controlled conditions. Indeed, the Medtronic catheter at issue here, like all Class III medical devices, is so-classified because it is used "in supporting or sustaining human life." 21 U.S.C. § 360c(a)(1)(C)(ii)(I). Congress subjected these devices to the stringent federal regulatory oversight of the PMA process because they intrinsically "present[] a potential unreasonable

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[10] Although not presented in this appeal, this is not to suggest that all state tort claims with respect to a PMA-approved medical device necessarily would be preempted. It may be the case that certain manufacturing flaw claims—those premised not on a challenge to the overall FDA-approved manufacturing process but on the specific device the patient received containing a manufacturing flaw reflecting a deviation from the FDA-approved design and manufacturing process—would survive a preemption analysis. *See, e.g.*, Pet. App. 35a (addressing manufacturing flaw claim that otherwise failed to survive summary judgment).

risk of illness and injury." *Id.* § 360c(a)(1)(C)(ii)(II); see *Lohr*, 518 U.S. at 477 (juxtaposing § 510(k) review and explaining that FDA takes, on average, 1,200 hours to review a PMA application). Yet Congress freed such devices from additional state regulatory requirements, thereby facilitating continued innovation.

AdvaMed's members alone spend roughly $9 billion annually on research and development to facilitate device innovations. Even a decade ago, this trajectory was evident: In 1995, the average research and development expense underlying a PMA-approved device was approximately $75 million, a three-fold increase from 1990. See William W. George, *Medical Technology and Competitiveness in the World Market: Reinventing the Environment for Innovation*, 50 Food & Drug L.J. 477, 480 (1995). In addition to threshold research and development costs, the PMA application itself imposes significant costs. The United States Government Accountability Office found that user fees charged by FDA for PMA review of a device averaged over $239,000 per device in 2005. GAO-06-62, *Medicare Durable Medical Equipment: Class III Devices Do Not Warrant a Distinct Annual Payment Update* 3 (Mar. 1, 2006). And, over ten years ago, FDA estimated that PMA applications and supplements cost the industry approximately $35 million per year. See 62 Fed. Reg. 51112, 51113 (Sept. 30, 1997).

These costs, and the length of PMA approval, contribute to a background "pipeline problem" in bringing new and innovative medical products to market that is further exacerbated by state tort liability risks. See generally FDA, *Innovation or Stagnation*, *supra*, at 1 (recognizing a "growing crisis in moving basic discoveries to the market where they can be made available to patients"); *id.* (noting the decrease in the number of device applications). FDA recently expressed its "growing concern that many of the new basic science discoveries made in recent years may not quickly yield more effective, more affordable, and safe medical products for

patients. This is because the current medical product development path is becoming increasingly challenging, inefficient, and costly." *Id.*

The American Medical Association has observed that "[i]nnovative new products are not being developed or are being withheld from the market because of liability concerns or inability to obtain adequate insurance." Am. Med. Ass'n Bd. of Trs., *Impact of Product Liability on the Development of New Medical Technologies* 1 (1988). It remains difficult to properly insure against state tort risks.[11]

"[M]edical equipment companies are increasingly reluctant to innovate because of concern about suits with larger numbers of claimants and extraordinary awards." Lawrence Tancredi & Dorothy Nelkin, *Medical Malpractice and Its Effect on Innovation* 251, 260, *in The Liability Maze* (P.W. Huber & R.E. Litan eds., 1991). "The threat of . . . enormous awards has a detrimental effect on the research and development of new products. Some manufacturers of prescription drugs, for example, have decided that it is better to avoid uncertain liability than to introduce a new pill or vaccine into the market." *Browning Ferris Indus. of Vt., Inc.* v. *Kelco Disposal, Inc.*, 492 U.S. 257, 282 (1989) (O'Connor, J., concurring in part and dissenting in part).

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[11] *See, e.g.*, David Dial et al., *Tort Excess 2005: The Necessity for Reform from a Policy, Legal and Risk Management Perspective* 9-10 (2005) ("[t]he unpredictable and catastrophic nature of U.S. tort exposures . . . has made insuring large-scale liability risks substantially more challenging" in recent years, and "the scarcity of coverage" for pharmaceuticals "has reached critical proportions"); Scott E. Harrington, *Tort Liability, Insurance Rates, and the Insurance Cycle, Brookings-Wharton Papers on Financial Services* (2004) ("An expanding tort liability system that entails substantial uncertainty about the cost of future claims will inevitably lead to increasingly expensive [insurance] coverage.").

Numerous commentators have remarked on this phenomenon.[12] For example, Professor Michael E. Porter of the Harvard Business School has explained that in the United States "product liability is so extreme and uncertain as to *retard innovation*" because "the legal and regulatory climate places firms in constant jeopardy of costly and, as importantly, lengthy product liability suits" and "goes beyond any reasonable need to protect consumers." Michael E. Porter, *The Competitive Advantage of Nations* 649 (1990) (emphasis added). State tort exposure's "profound negative impact on the development of new medical technologies," AMA, Bd. of Trs., *supra*, at 1, unfortunately reflects a reasoned response by manufacturers to pull back in the face of unreasonable and unpredictable liability.

Similarly, the threat of liability skews device-development incentives in a manner that can undermine public health. For example, FDA has recognized that rising costs create incentives for manufacturers to focus on low risk, high profit products. See generally FDA, *Innovation or Stagnation* ("Because of rising costs, innovators often concentrate their efforts on products with potentially high market return."). At the same time, manufacturers are discouraged from

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[12] *See, e.g.*, Louis Lasagna, *The Chilling Effect of Product Liability on New Drug Development in The Liability Maze* 34, 337, *supra* ("concern about liability has led to serious delays in product development and to increased liability insurance costs"); W. Kip Viscusi & Michael J. Moore, *An Industrial Profile of the Links Between Product Liability & Innovation in The Liability Maze* 81, 83, 94-96, *supra* (recognizing that product liability can cause lags in drug development and that losses exceeded premiums for insurers of pharmaceutical companies throughout the 1980s); W. Kip Viscusi, et al., *A Statistical Profile of Pharmaceutical Industry Liability, 1976-1989*, 24 Seton Hall L. Rev. 1418, 1434 (1994) ("The pharmaceutical industry, which is one of the most innovative industries in the economy, has been particularly hard hit by the surge in liability costs."); *id.* at 1419 (recognizing that a National Academy of Science panel also found that increased liability costs had discouraged innovation in the pharmaceutical industry).

developing medical treatments which, despite potentially life-saving benefits, also pose heightened risks. See *id.* ("For very innovative and unproven technologies, the probability of an individual product's success is highly uncertain, and the risks are perceived as extremely high."); see also *id.* ("[i]nventors of candidate artificial organs, bioengineered tissues, and other novel devices face serious challenges and uncertainties").

### B. State Tort Liability Threatens The Availability Of Significant Medical Treatments.

The specter of state liability threatens the availability of important medical treatments and can have a chilling effect on marketing treatments in the United States that are available abroad. Historically, this phenomenon has been particularly acute in the area of women's health.

Bendectin, the only prescription medication approved by FDA for treating significant morning sickness during pregnancy, provides a classic example of this dynamic. See Lasagna, *supra*, at 337-41. Extreme morning sickness can have a devastating medical impact both on the pregnant woman and on the developing child and requires medical treatment. Although no scientifically reliable study ever found a causal relationship between the medication and birth defects, and FDA repeatedly found the product to be safe and effective, the manufacturer faced nearly 2,000 tort suits seeking to recover for alleged birth defects. See generally Dep't of Health & Human Servs., FDA, Determination That Bendectin Was Not Withdrawn From Sale For Reasons Of Safety Or Effectiveness, 64 Fed. Reg. 43190 (Aug. 9, 1999). And even though its manufacturer was successful in defending the litigation on the merits, Bendectin was withdrawn from the market in 1983, in light of $18 million per year insurance and legal costs, as compared to only $20 million in annual sales. See, *e.g.*, Marvin E. Jaffe, *Regulation, Litigation and Innovation in the Pharmaceutical Industry: An Equation for Safety, in Product Liability & Innovation: Managing Risk in an Uncertain Environment*

120, 126 (J.R. Hunziker & T.O. Jones eds., 1994); Lasagna, *supra*, at 338 ("[Bendectin's] doom was traceable to the flood of legal actions that followed assertions in the scientific literature that Bendectin could produce congenital defects in both animals and humans.").

This experience has had a ripple effect in discouraging the future development of morning sickness treatments in the United States. See Lasagna, *supra*, at 341 (stating that after the Bendectin experience "[i]t seems safe to predict" that no manufacturer will seek FDA approval for a morning sickness drug). In the absence of a viable treatment such as Bendectin, "treatment for severe nausea during pregnancy" accounted for "nearly $40 million of the nation's annual hospital bill" in 1994 alone, and "[i]t is unlikely that any new drug will be developed to close this therapeutic gap." Jaffe, *supra*, at 126. Moreover, since the withdrawal of Bendectin from the United States market, hospitalizations due to severe morning sickness have increased three-fold in the United States, while such hospitalizations have declined, for example, in Canada, where the drug has remained available under the name "Diclectin." FDA/NIH Conference, *Clinical Pharmacology During Pregnancy Addressing Clinical Needs Through Science* (Dec. 4, 2000), *available at* www.fda.gov/cder/present/clinpharm2000/1204preg.txt; see C. Ineke Neutel, *Variation In Rates of Hospitalization for Excessive Vomiting In Pregnancy By Bendectin/Diclectin Use in Canada, available at* www.nvp-volumes.org/p1_9.htm ("What is then the impact of the withdrawal of Bendectin? The increase of hospitalization for [excessive vomiting in pregnancy] for thousands of women for more than a decade led to increased cost and hardship to the women and their families, as well as to the healthcare system.").

The withdrawal of Norplant from the United States market also illustrates the point. Norplant, a set of implanted rods that release a hormone to inhibit ovulation, was acclaimed upon introduction to the market in 1991 and had

approximately one million users by 1995. See Linda A. Johnson, *Wyeth Won't Resume Norplant Sales*, Associated Press Online, July 26, 2002; Albert George Thomas Jr. & Stephanie M. LeMelle, *The Norplant System: Where Are We in 1995*, 40 J. Fam. Prac. 125, 125 (1995). FDA repeatedly found Norplant to be an effective method of birth control. See, *e.g.*, Johnson, *supra*; Sylvia A. Law, *Sex Discrimination & Insurance for Contraception*, 73 Wash. L. Rev. 363, 371 (1998) ("Norplant has been subject to extensive testing and appears to be highly effective and safe."). Yet Norplant was withdrawn from the United States market in August 2000, amidst allegations that certain individual lots might not be effective. See Johnson, *supra*.

Despite positive public health findings by FDA, the World Health Organization, and the American Society of Reproductive Medicine, commentators have observed that Norplant was "'killed off,'" as lawsuits based on "untru[ths]" and "misperceptions" hurt sales, and Norplant's manufacturer made a "business decision" to no longer market the product. Johnson, *supra*; Gina Kolata, *Will the Lawyers Kill Off Norplant?*, N.Y. Times, May 28, 1995, at C1.[13] Even the company's "'legal success has come at a steep price because lawsuits are time consuming, expensive and have a chilling effect on research.'" Morrow, *supra* (quoting manufacturer's North American President).

In the end, litigation stifled a medical treatment that was beneficial to many women, leaving in its wake a poor climate for future development of contraceptive devices. As Dr. Felicia Stewart, then-deputy assistant for population affairs at

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[13] Over the course of Norplant litigation, more than 50,000 plaintiffs purportedly sued the company. *See Contraceptive Maker Wins Woman's Suit Over Side Effects*, N.Y. Times, Sept. 5, 1998. No plaintiff won a jury verdict and the manufacturer won multiple trials, numerous summary judgment motions, and had tens of thousands of cases dismissed. David J. Morrow, *Maker of Norplant Offers a Settlement in Suit Over Effects*, N.Y. Times, Aug. 27, 1999.

the Department of Health and Human Services, recognized "'[i]t's clear watching what happened with Norplant why a company thinking about marketing a new contraceptive product might say it isn't worth making an investment.'" Kolata, *supra*; see, *e.g.*, Johnson, *supra* (noting that the manufacturer also declined to introduce a successor device to the United States market although it had done so abroad); Anna Biernbaum, Note, *Shielding the Masses: How Litigation Changed the Face of Birth Control*, 10 S. Cal. Rev. L. & Women's Stud. 411, 412-13 (2001) ("Due to the bad publicity Norplant received, few women are using this safe and effective form of birth control. . . . [T]here is no longer an incentive for drug companies to research and market new birth control devices, since the threat of litigation is something that they are keenly aware of in the wake of Norplant."). Under the rule for which petitioner and her *amici* advocate, there is no reason to believe that the threats to innovation will be any less severe with respect to PMA-approved medical devices.

### C. State Tort Liability Increases Price And Undermines The Affordability Of Medical Treatments.

State tort liability increases the price of medical therapies. See, *e.g.*, Barbara Marsh, *The Product Liability Morass; Complications Set In; Big Suppliers Pulling Out of Medical Market*, L.A. Times, May 6, 1995, at A1. For example, manufacturers of certain catheters, heart valves and other devices were forced to withdraw from the market when silicone prices increased to $100 per pound from $6 per pound due to product liability litigation. *Id.* Vaccines provide another example of the point. Between 1980 and 1989, the wholesale price of most vaccines doubled or tripled; in contrast, the price of two vaccines with a higher perceived liability potential increased by factors of 40 and seven in the same period. Richard L. Manning, *Changing Rules in Tort Law and the Market for Childhood Vaccines*, 37 J. L. & Econ. 247, 254-57, 273 (1994) (describing, respectively, the

increased price of the diphtheria, pertussism and tetanus (DPT) vaccine and the oral polio vaccine).

In setting the price of medical therapies, not only must a manufacturer recoup its research, development, and production costs through device sales—a goal managers of publicly held companies may have a fiduciary duty to pursue—but it also must insure against litigation risks. As described above, companies "often have to self-insure" against the prospect of large tort awards in a climate of "present and future risks that are almost impossible to quantify but that may be potentially large enough to include financial catastrophe for the manufacturer." Lasagna, *supra*, at 337. Moreover, endeavoring to comply with 50-plus divergent state standards governing the marketing, design, and labeling of a device—rather than a single federal standard—would pose considerable incremental costs that would be reflected in increased price.

### D. State Tort Liability Encourages Defensive Labeling And Overwarning That Undermine Rational Prescribing By Physicians.

FDA has cautioned that state common-law tort actions which "encourage, and in fact require, lay judges and juries to second-guess" FDA's balancing of the benefits and risks of a specific device, create pressures for "'defensive labeling' . . . resulting in scientifically unsubstantiated warnings and underutilization of beneficial treatments." Br. *Amicus Curiae* of the United States at *25-26, *Horn*, *available at* 2004 WL 1143720 (filed 3d Cir. May 14, 2004) (recognizing potential harm to public health); cf. 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) ("[A]dditional [state-law] requirements for the disclosure of risk information are not necessarily more protective of patients. Instead, they can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use.").

In an attempt to avoid state liability where plaintiffs allege they were not adequately warned of a particular risk, manufacturers have an inappropriate incentive to disregard FDA's expert judgment about the proper balance of risk information and instead warn of each and every conceivable risk of using the product, no matter how remote. This creates a serious danger that manufacturers include warnings with respect to medical devices that are not scientifically substantiated and overemphasize warnings as to marginal risks—thereby inappropriately de-emphasizing more serious risks.

Defensive labeling is far from benign. A physician's prescription decision is rational only when he or she has an accurate understanding of the risks and benefits of the prescription device under consideration and can compare those risks and benefits to those associated with other treatment alternatives. A fog of unmanaged warnings, unfiltered by FDA's expert judgment, impairs the ability of prescribing physicians to properly assess whether the potential benefits of the therapy for a particular patient outweigh its potential risks. Defensive labeling may cause physicians to prescribe a treatment that is riskier than they realize because serious risks are obscured in a blur of low risks, and may ultimately dissuade physicians from prescribing (and patients from undergoing) therapies that have more potential good than harm for a given patient because of unsubstantiated fears.[14]

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[14] *See, e.g.*, Horn *Amicus* Br., *supra*, at 25-26; *Brooks*, 273 F.3d at 797; W. Kip Viscusi, *Individual Rationality, Hazard Warnings, and the Foundations of Tort Law*, 48 Rutgers L. Rev. 625, 665-66 (1996) ("Excessive warnings are not innocuous. If warnings indicate a high relative risk when there is none, they will distort relative product comparisons, thus compromising credibility. Similarly, if warnings are included for inconsequential risks, they will serve to further dilute the warnings for the real hazards that should be identified to consumers."); Lars Noah, *The Imperative to Warn: Disentangling the "Right to Know"*

Inappropriate incentives with respect to defensive warnings are particularly acute given that "[t]ime and again, one sees how an avalanche of lawsuits can be set loose by a tiny hiccup of error in scientific research." Peter Huber, *Junk Science in the Courtroom*, Forbes, July 8, 1991, at 68. The following example illustrates the point:

> [L]awyers won a spectacular $5.1 million verdict . . . largely on the strength of a single study that had very tentatively suggested that spermicides might cause birth defects. Not quite two years after the verdict, however, the several authors of that study spoke out again. One acknowledged that their work "was not corroborated by subsequent studies," and that their "study's definition of exposure to spermicide near the time of conception was grossly inaccurate." Another conceded: "I believe our article should never have been published. In our present litigious environment, the reservations and qualifications written into a published report are often ignored, and the article is used as 'proof' of a causal relationship." [*Id.*[15]]

Tort risks such as these encourage "defensive labeling."

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*From the "Need to Know" About Consumer Product Hazards*, 11 Yale J. on Reg. 293, 380 (1994) (discussing dangers of overwarning and recognizing that FDA "generally frowns upon and will not approve defensive labeling").

[15] A similar research "blip" occurred recently with respect to drug-coated heart stents—stents with a drug coating to help minimize re-narrowing of heart structures following surgery. Last year, researchers presented preliminary data at academic conferences "that suggest[ed] a small but significant increased risk of stent thrombosis [*i.e.*, blood clots] in patients who have drug-eluting stents" as opposed to bare-metal stents FDA, *FDA Statement on Coronary Drug-Eluting Stents* (Sept. 14, 2006). FDA concluded that the drug-coated stents remained safe and effective, and pledged further study. *See id.* Soon thereafter, the same researchers concluded (after completing an additional year of study) that there was *no* statistically significant difference in the risk posed by drug-coated stents. *See* Maria Cheng, *New Study: Drug-Coated Stents Not So Bad*, Associated Press Online, Sept. 2, 2007.

## CONCLUSION

For these reasons, as well as those set forth in respondent's brief, the decision below should be affirmed.

Respectfully submitted,

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IN THE

# Supreme Court of the United States

CHARLES R. RIEGEL AND DONNA S. RIEGEL,

*Petitioners,*

*v.*

MEDTRONIC, INC..

*Respondent.*

**On Writ Of Certiorari to the United States Courts of Appeals for the Second Circuit**

## AMICUS CURIAE BRIEF OF THE AMERICAN ASSOCIATION FOR JUSTICE AND PUBLIC JUSTICE IN SUPPORT OF PETITIONERS

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## TABLE OF CONTENTS

TABLE OF AUTHORITIES ..... iii

IDENTITY AND INTEREST OF *AMICI CURIAE* ..... 1

SUMMARY OF THE ARGUMENT ..... 2

ARGUMENT ..... 4

I. IN ENACTING THE MEDICAL DEVICE AMENDMENTS, CONGRESS DID NOT CLEARLY AND UNAMBIGUOUSLY PREEMPT PRIVATE CAUSES OF ACTION FOR INJURY CAUSED BY UNSAFE DEVICES. ..... 4

A. Congress Enacted the Medical Device Amendments To Protect Consumers By Expanding the FDA's Pre-Marketing Authority, Not To Protect Device Makers from Post-Marketing Liability ..... 5

B. The Court Below Failed to Interpret the MDA's Express Preemption Provision Consistent With the Strong Presumption Against Preemption of State Law Remedies for Personal Injury ..... 8

II. A STATE DOES NOT ESTABLISH A REQUIREMENT WITH RESPECT TO A DEVICE WHEN A JURY RETURNS A VERDICT FOR THE PLAINTIFF IN A PRODUCT LIABILITY ACTION ..... 10

A. General Common-Law Duties Establish No Requirement "With Respect To A Device." ..... 10

B. A Verdict In Plaintiff's Favor Does Not Establish A "Requirement" With Respect to a Device. ..... 12

III. CONGRESS DID NOT INTEND TO ELIMINATE TRADITIONAL STATE TORT REMEDIES AND RELY SOLELY ON FDA REGULATIONS TO ENSURE THE SAFETY OF MEDICAL DEVICES. ..... 15

A. Product Liability Plays a Distinct and Important Role Protecting Public Safety ..... 15

B. Congress Would Not Have Intended To Ensure the Safety of the Most Potentially Dangerous Devices Through Regulation Alone. ..... 22

CONCLUSION ..... 27

# TABLE OF AUTHORITIES

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## IDENTITY AND INTEREST OF *AMICI CURIAE*

The American Association for Justice ["AAJ"], formerly the Association of Trial Lawyers of America, and Public Justice respectfully submit this brief as *amici curiae*. The parties have filed letters of consent to the filing of amicus briefs.[1]

AAJ is a voluntary national bar association whose approximately 52,000 trial lawyer members primarily represent individual plaintiffs in civil suits and personal injury actions, including plaintiffs injured by unsafe medical devices. Throughout its 40-year history, the association has championed the fundamental right of every American to legal recourse for redress of wrongful injury. AAJ views the lower court's decision in this case as an unwarranted expansion of the preemption doctrine that undermines that fundamental right.

Public Justice is a national public interest law firm dedicated to pursuing justice for the victims of corporate and governmental abuses. Through involvement in precedent-setting and socially significant litigation, Public Justice seeks to ensure that tort law fully serves its dual purposes – compensating those injured by wrongful conduct and deterring similar conduct in the future. Public Justice is gravely concerned that, if the tort system is closed to innocent victims of defective medical devices through application of the preemption doctrine in this case, neither of these purposes will be served.

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[1] Pursuant to Rule 37.6, Amici disclose that no counsel for a party authored any part of this brief, nor did any person or entity other than Amici Curiae, their members, or counsel make a monetary contribution to its preparation.

## SUMMARY OF THE ARGUMENT

1. The court below erred in holding that the Medical Device Amendments of 1976 expressly preempt not only state administrative regulation of devices, but also state product liability damage lawsuits.

Congress enacted the MDA to expand the authority of the FDA to keep unsafe medical devices off the market before they could cause injury. Lawmakers were responding to the harms caused by the Dalkon Shield and other unsafe medical devices that had resulted in numerous lawsuits. Congress did not respond by protecting manufacturers from liability for such injuries. In fact, there is no indication in the legislative history that Congress sought to eliminate state-law remedies for injury. Rather, Congress saw this litigation as symptomatic of a regulatory shortfall. Its response was to fill this gap by enacting *additional* tools for protecting the public.

The most important of this Court's canons of construction regarding preemption provisions is the presumption against preemption. Congress must be presumed to have intended to leave state law remedies in place in the absence of clear and unambiguous intent to the contrary. The court below, however, construed § 360k through preemption-colored glasses, holding that a State "requirement" *should* include common-law actions simply because it *could* be so construed.

2. The court below erred in holding that plaintiffs' product liability action, if successful, would impose a state requirement different from the federal requirement under the MDA. Although preemption of state requirements may in some circumstances encompass common law duties, Congress narrowly

wrote the MDA to preempt only state requirements "with respect to a device." Plaintiffs' causes of action in this case are based on the duties imposed on all manufacturers to exercise due care under the circumstances in designing products and warning of their dangers. These general common law duties are not requirements with respect to medical devices.

Nor are plaintiffs' causes of action preempted on the theory that a jury verdict would establish a requirement with respect to the specific device in this case. A jury is not a "State or political subdivision of a State." Moreover, a jury verdict in plaintiff's favor imposes no requirement upon the defendant apart from the obligation to pay compensation. Although a verdict may motivate the defendant to change a product to avoid future liability, such a financial incentive does not amount to a "requirement." The Supremacy Clause and the preemption doctrine are not concerned with speculative influences on private decisionmaking.

3. The court below erred in basing its holding on the notion that Congress intended to rely solely upon FDA regulation to ensure the safety of the most potentially dangerous medical devices – those subject to PMA approval.

For nearly a century, America has relied on a two-pronged approach to consumer product safety. Government regulation overrides the marketplace and imposes safety directly by decree. Product liability, on the other hand, operates indirectly through the marketplace. By requiring the manufacturer to internalize the costs of injury as part of the price of the product, the market creates a financial incentive for manufacturers to make their products reasonably safe. These two approaches to

product safety are radically different, and this Court has consistently held that Congress can intend to preempt state regulatory requirements while leaving in place the indirect effects of tort awards.

Indeed, as Congress was undoubtedly aware, courts have traditionally viewed regulation and liability as complementary approaches to product safety. Courts have harmonized those approaches in the well-settled rule that compliance with regulatory requirements is evidence of, but not conclusive of, due care.

There is no evidence that Congress intended to rely exclusively on FDA regulation to ensure the safety of potentially dangerous medical devices. Congress was well aware of the limitations on the agency's abilities to protect the public. Moreover, Congress would not have eliminated without comment the consumer's right to seek legal remedy for wrongful injury. This Court has recognized that right as fundamental for over two hundred years. Congress should not be presumed to have cast it aside without clear indication that it intended to take so drastic a step.

## ARGUMENT

### I. IN ENACTING THE MEDICAL DEVICE AMENDMENTS, CONGRESS DID NOT CLEARLY AND UNAMBIGUOUSLY PREEMPT PRIVATE CAUSES OF ACTION FOR INJURY CAUSED BY UNSAFE DEVICES.

The court below erred in ruling that, because an express preemption of state "requirements" *could* encompass common law remedies, the MDA *should*

be so interpreted, disregarding the strong presumption that Congress intended to leave the matter of remedy for wrongful injury to the States.

### A. Congress Enacted the Medical Device Amendments To Protect Consumers By Expanding the FDA's Pre-Marketing Authority, Not To Protect Device Makers from Post-Marketing Liability.

*Amici* address this Court on an important and dispositive issue in this case: Whether an individual's product liability claim is a state "requirement" that is expressly preempted by the Medical Device Amendments of 1976, 21 U.S.C. § 360k. The lower court held that § 360k(a) preempts not only the positive law of a state – legislative and administrative regulation – but also an individual's private cause of action for personal injury. *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 120-23 (2d Cir. 2006).

In 1976, Congress took a dramatic step to protect the health and safety of Americans. Congress recognized that new and sophisticated medical devices, particularly those designed to be placed inside the body, pose a serious risk of harm to consumers. S. Rep. No. 94-33, at 5 (1976), *reprinted in* 1976 U.S. Code & Admin. News 1070, 1074. Injuries to women caused by the Dalkon Shield IUD, for example, resulted in more than 500 lawsuits seeking compensation. H.R. Rep. No. 853, at 8 (1976). In 1976, Dalkon Shield lawsuits were the largest category of product liability actions pending in federal courts, outnumbering even asbestos cases. U.S. General Accounting Office, Product Liability: Extent of "Litigation Explosion" in Federal Courts Questioned, HRD-88-36BR (Jan. 1988) at 22.

Congress responded to the numerous injuries linked to harmful medical devices not by declaring a need to protect device makers from lawsuits, but by creating *additional* tools to prevent future tragedies. Indeed, "the entire legislative history reveals no mention of preempting state common law tort claims." Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 923 n.128 (1994). It was private litigation, not the efforts of the Food and Drug Administration, that brought the problems of unsafe devices to lawmakers' attention. *Id.* at 944-45.

Congress saw these injury lawsuits as symptomatic of a serious regulatory shortfall. The FDA had acted swiftly to remove the Dalkon Shield from the market, but it was too late for thousands of women who suffered toxic shock, infertility, and pelvic infections.[2] The question that concerned Congress was not whether the manufacturers should be held liable for injuries, but rather why the FDA could not keep unsafe devices off the market in the first place. Of particular concern were the Dalkon Shield, catheters, artificial heart valves, defibrillators, and pacemakers. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 476 (1996). These devices "became the symbols that spurred Congressional action to protect the public from the harmful effects of a largely unregulated device industry." *Ministry of Health v. Shiley, Inc.*, 858 F. Supp. 1426, 1434 (C.D.

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[2] The story of the Dalkon Shield scandal is told in *In re A.H. Robins Co.*, 880 F.2d 709, 710-12 (4th Cir.), *cert. denied*, 493 U.S. 959 (1989); and in Richard B. Sobol, BENDING THE LAW: THE STORY OF THE DALKON SHIELD BANKRUPTCY (1991).

Cal. 1994). Witness after witness in congressional hearings blamed the numerous injuries and deaths caused by medical devices on the FDA's inability to assure their safety prior to marketing. *See* S. Rep. No. 94-33, at 7-10 (1976), *reprinted in* 1976 U.S. Code & Admin. News 1070, 1076-79.

At that time, the FDA possessed no specific authority to regulate the entry of medical devices into the market, as it possessed with respect to drugs. H.R. Rep. No. 853, at 2-3 (1976). The agency had authority to monitor and regulate the sale of medical devices. *See* 21 U.S.C. § 331 (1994) (prohibiting commerce in adulterated or misbranded medical devices). But its enforcement powers were limited to recalls and other post-marketing actions.

To fill this gap, Congress passed the Medical Device Amendments ["MDA"], which created a regulatory structure for the FDA to require that medical devices be shown to be safe and effective prior to entering the market. Pub. L. No. 94-295, 90 Stat. 539 (1976) (codified at 21 U.S.C. § 360c et seq.). The statute's overriding purpose was to "provide for the safety and effectiveness of medical devices intended for human use." 90 Stat. 539 (preamble).

Congress included in the MDA an express preemption provision:

> (a) General rule. Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> (1) which is different from or in addition to, any requirement applicable under this Act to a device, and

> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

21 U.S.C. § 360k(a).

The question before the Court is whether Congress intended this provision to prevent future victims from bringing state-law tort actions for harms caused by unsafe medical devices that have managed to reach the marketplace. The answer is clearly "No."

### B. The Court Below Failed to Interpret the MDA's Express Preemption Provision Consistent With the Strong Presumption Against Preemption of State Law Remedies for Personal Injury.

This Court's "canons of construction" for interpreting express preemption provisions are well-known. The intent of Congress provides the "touchstone" in matters of federal preemption of state law. *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992); *Lohr*, *supra*, 518 U.S. at 485. Courts ascertain congressional intent from the plain wording of a preemption provision, *Cipollone*, 505 U.S. at 523-24; *Lohr*, 518 U.S. at 484, as well as from "both textual and legislative context" of the statute. *Cipollone*, 505 U.S. at 519 n.16 (1992); *Lohr*, 518 U.S. at 489-90.

Most importantly, courts must assume that "the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Cipollone*, 505 U.S. at 518; *Lohr*, 518 U.S. at 485. This presumption is even stronger where, as here,

preemption would leave injured individuals without any legal remedy for wrongful injury. *Lohr*, at 487 (plurality), citing *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984). If congressional intent to eliminate state tort remedies is not unambiguously clear, it is not the role of the courts to supply it.[3]

The court below did not reject the presumption against preemption, but it nevertheless read the statutory language through preemption-colored lenses. It reasoned that, because "a state 'requirement,' for purposes of the MDA, *could* stem from state common-law actions," then "Section 360k(a)'s reference to state 'requirements' *should* be interpreted to encompass state common law actions." 451 F.3d at 116 & 123 (emphasis added).

The presumption applied by the lower court was clearly one that *favored* preemption. In fact, the court turned the presumption completely upside down, shifting the onus to Congress to "amend Section 360k(a) to make clear that its reference to state 'requirements' does not include state tort actions." 451 F.3d at 124.

This approach flies in the face of this Court's repeated teachings that congressional silence is not a sufficient basis for extending the scope of express preemption beyond state positive law to encompass common-law remedies. *See, e.g., Sprietsma v. Mercury Marine*, 537 U.S. 51, 69 (2002) (provision of the Federal Boat Safety Act, 46 U.S.C. § 4306,

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[3] "When judges preempt state laws in the absence of explicit congressional guidance, they in effect assume a legislative role without accepting legislative responsibility." Kenneth Starr, et al., The Law of Preemption: A Report of the Appellate Judges Conference of the American Bar Association 48 (1991).

preempting state laws, regulations, or standards "imposing a requirement," does not also preempt tort claims where the statute does not convey Congress's "clear and manifest intent to sweep away state common law."); *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 452 n.26 (2005) (in Federal Insecticide, Fungicide, and Rodenticide Act, express preemption of state "requirements" does not include tort remedies where "the lengthy legislative history is barren of any indication that Congress meant to abrogate most of the common-law duties long owed by pesticide manufacturers."); *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 868 (2000) (preemption of state "standards" does not include tort actions where the Court "found no convincing indication that Congress wanted to pre-empt, not only state statutes and regulations, but also common-law tort actions.").

## II. A State Does Not Establish a Requirement With Respect To A Device When A Jury Returns A Verdict For The Plaintiff In A Product Liability Action.

The court below erred in holding that a verdict in plaintiff's favor in a product liability case results in a requirement established by the State.

### A. General Common-Law Duties Establish No Requirement "With Respect To A Device."

This Court has indicated that express preemption of state "requirements" could, in some circumstances, embrace general common law duties. *Cipollone*, 505 U.S. at 522; *Bates*, 544 U.S. at 443. However, Congress wrote 21 U.S.C. § 360k(a)

narrowly. Its preemptive scope includes only a requirement "with respect to a device." A majority of this Court has held that the MDA's preemption of any state "requirement" does not include "general state common-law requirements," such as "the general duty of every manufacturer to use due care to avoid foreseeable dangers in its products." *Lohr*, 518 U.S. at 501 (Part V).

Plaintiffs in this case have alleged negligence in design, negligent failure to warn, strict liability, and breach of implied warranty. Such general duties, as the Court pointed out, "were not specifically developed "with respect to" medical devices." *Id.*

Additionally, these duties merely create a financial incentive for a manufacturer to exercise due care under the circumstances. The focus of the inquiry is whether the manufacturer acted reasonably in marketing a product with a known and preventable risk of injury. David G. Owen, *Proving Negligence in Modern Products Liability Litigation*, 36 Ariz. St. L.J. 1003, 1003 (2004). Applicable New York product liability law is no different:

> New York courts generally consider design defect and negligence claims "functionally synonymous," . . . Ultimately, the inquiry in a design defect case 'requires a fact finder to make a judgment about the manufacturer's judgment' in choosing to design a product in a certain way.

*Barban v. Rheem Textile Sys., Inc.*, 2005 WL 387660, at *7 & *8 (E.D.N.Y. 2005) (citations omitted).

Thus, these common law duties merely relate to a manufacturer's *conduct*; they do not impose any specific requirement with respect to the design of the product itself.

### B. A Verdict In Plaintiff's Favor Does Not Establish A "Requirement" With Respect to a Device.

The court below, responding to plaintiff's argument that § 360k does not encompass general common law duties, shifted its focus to jury *verdicts*. The court stated that, "a verdict [in the Riegels' favor] would clearly differ from the FDA's PMA approval of the device." *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 114 (2d Cir. 2006). Thus, the court reasoned, "the Riegels' claim, if successful, would result in state 'requirements' that differed from or added to those [federal] standards." *Id.* at 122.

The court viewed this case as "quite analogous to the hypothetical situation posed by Justice Breyer in his *Lohr* concurrence." *Id.*

Justice Breyer posited a federal MDA regulation that requires a 2-inch wire in a hearing aid. The wire, however, caused serious injury to a consumer, a known danger that could have been avoided if the manufacturer had used a shorter wire. Justice Breyer suggested that "an award by a jury persuaded by expert testimony that use of a more than 1-inch wire is negligent" would establish a requirement different than the MDA regulation.[4] Suggesting that the effects of such a jury verdict would be "identical" to a state agency regulation requiring a 1-inch wire, Justice Breyer questioned whether the state tort action should also be preempted. 518 US. at 504-05.

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[4] It is not indicated whether the hypothetical manufacturer alerted the FDA to the hazard presented by the 2-inch wire or whether the company sought to modify the regulation, matters that would be probative of due care under the circumstances.

For several reasons, the court below erred in relying on this hypothetical. First, as Justice Breyer himself indicated, § 360k is "highly ambiguous" and "Congress likely did not focus specifically upon the matter." *Id.* at 504-05.[5] Such a showing, he concluded, is not sufficient to surmount the presumption against preemption. *Id.* at 505. As the Court explained in connection with another statute expressly preempting state "requirements":

> Even if Dow had offered us a plausible alternative reading of § 136v(b) – indeed, even if its alternative were just as plausible as our reading of that text – we would nevertheless have a duty to accept the reading that disfavors pre-emption.

*Bates, supra,* 544 U.S. at 449.

Second, characterizing jury verdicts as state requirements does violence to the plain language of § 360k. A jury cannot comfortably be deemed a "State or political subdivision of a State." That usage is even less sensible in this case, where the role of the State would be played by a *federal* jury or *federal* judge rendering a verdict in this diversity case. Nor in common usage does a jury "establish or continue in effect" its verdict.

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[5] Given the lawmakers' overriding concern with FDA's premarketing authority, it is likely Congress saw no conflict with post-marketing liability. As one court has noted, "the legislative history recounts the difficulty the FDA experienced in its earlier attempts to keep dangerous medical devices out of the marketplace." "This attention to the regulation of medical devices *before* they reach the marketplace is consistent with" the absence of any expressed intent to affect manufacturers' liability after devices are sold. *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1378 (11th Cir. 1999) (emphasis in original).

Finally, and most importantly, the effects of state regulation and the effects of a jury verdict in a tort action are *not* identical. As trial lawyers are well aware, a jury verdict in favor of the plaintiff in a products liability case, requires nothing more than that the defendant compensate the plaintiff for the harm caused. See Philip H. Corboy and Todd A. Smith, *Federal Preemption of Product Liability Law: Federalism and the Theory of Implied Preemption,* 15 Am. J. Trial Adv. 435, 455-57 (1992); Ralph Nader and Joseph A. Page, *Automobile-Design Liability and Compliance With Federal Standards* 64 Geo. Wash. L. Rev. 415, 437-39 (1996).

A manufacturer may be influenced by a verdict to change the design of its product, but it is not required to do so. The product may already have been taken off the market or replaced by a newer, safer model. The manufacturer may decide to address the hazard by a warning or by a design change not considered by the jury. It could also rationally decide, balancing the probability of future serious harm against the cost of eliminating the risk, simply to compensate any future victims. Stephen Breyer, REGULATION AND ITS REFORM 175 (1982). In fact, most manufacturers sued for injury caused by their products do *not* change the product's design.[6]

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[6] Risk managers of Fortune 1000 corporations with actual product liability experience reported that as a result (1) over 35% had improved their product warnings and/or instructions; (2) over 30% had improved the safety of their designs and (3) 65% had established formal safety objectives. E. Patrick McGuire, The Impact of Product Liability 18 (Conference Bd. 1988), summarized in W. Page Keeton et al., Products Liability and Safety--Cases and Materials 1033-34 (2d ed. 1989).

As this Court recently stated, a jury verdict that creates an economic incentive to invest in safety does not impose a "requirement" as that term is used in a preemption provision:

> An occurrence that merely motivates an optional decision does not qualify as a requirement. . . .
>
> A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.

*Bates*, 544 U.S. at 444-45.

The central concern of preemption is the exercise of power by the state or federal government. It is not concerned with the private choices by individuals and companies who remain free to select from variously attractive options. *See Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1540-41 (D.C. Cir. 1984).

## III. CONGRESS DID NOT INTEND TO ELIMINATE TRADITIONAL STATE TORT REMEDIES AND RELY SOLELY ON FDA REGULATIONS TO ENSURE THE SAFETY OF MEDICAL DEVICES.

The lower court erred in speculating that when Congress authorized the FDA to require premarket approval of medical devices, it intended to eliminate the longstanding reliance on post-marketing liability as a complementary means to achieve product safety.

### A. Product Liability Plays a Distinct and Important Role Protecting Public Safety.

The court below attempted to distinguish this Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), as limited to devices approved through premarketing notification (§ 510(k) process), rather

than through the more rigorous premarket approval ("PMA") process applicable to the catheter in this case.

In the court's view,

> [T]he PMA regime represented an entirely new approach of ensuring consumer safety through increased federal regulation and oversight. It is thus much less clear that the continuation of the previous tort remedies in the PMA context is consistent with the MDA's purpose.

451 F.3d 123.

The court offered no support for the proposition that Congress intended to pursue the goal of safety for the most potentially dangerous medical devices by eliminating common-law remedies for injured consumers, and relying on FDA regulation alone. Moreover, the court gave little heed to this Court's instruction to approach this question with "the general understanding of common-law damages actions" and their role in product safety. *Cipollone,* 505 U.S. at 521.

Mass production and mass marketing of consumer products has brought great progress and prosperity to Americans over the past century. But unreasonably dangerous products also pose grave risks of personal injury and death. Throughout this era, the United States has depended upon a two-pronged approach to ensuring product safety.

Governmental regulation assumes the marketplace cannot achieve the desired level of safety and instead imposes safety by decree. With respect to medical devices, the responsible agency is the Food and Drug Administration, first created in

1906 to regulate food safety and expanded in 1938 to cover drugs, medical devices and cosmetics.[7]

Product liability, on the other hand, allows the marketplace itself to provide the financial incentive for manufacturers to make their products safe. Product liability is an evolution of the fault principle adapted by common law courts to the modern marketplace, beginning with Justice Cardozo's landmark decision in *MacPherson v. Buick Motor Co.*, 111 N.E. 1050 (N.Y. 1916), more fully developed in *Greenman v. Yuba Power Products*, 377 P.2d 897 (Cal. 1963), and reaching its most widely adopted formulation in Restatement (Second) of Torts §402A (1965). *See generally*, Gary T. Schwartz, *The Vitality of Negligence and the Ethics of Strict Liability*, 15 Ga. L. Rev. 963 (1981).

Tort law has been called "law with a human face." Peter H. Schuck, *Introduction: The Context of the Controversy* 17, 21, in TORT LAW AND THE PUBLIC INTEREST (Peter H. Schuck ed., 1991). Its primary purpose is to compensate those who have been wrongfully injured. But product liability also plays an indirect role providing market incentives for safety. *See* John W. Wade, *On the Nature of Strict Tort Liability for Products*, 44 Miss. L.J. 825, 826 (1973).

It is well-accepted that in a marketplace in which all actors have perfect knowledge of risks, the

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[7] The FDA was originally called the Division of Chemistry, changed its name to the Food, Drug, and Insecticide Administration in 1927, and in 1930, adopted its current name. Sasha B. Rieders, *State Law Tort Claims and the FDA: Proposing a Consumer-Oriented Prescription in Medical Device Cases*, 25 Cardozo L. Rev. 1159, 1160 n.6 (2004).

market itself would provide the most efficient allocation of resources to produce reasonably safe products. Ronald H. Coase, *The Problem of Social Cost*, 3 J.L. & Econ. 1 (1960); Jon D. Hanson and Kyle D. Logue, *The First-Party Insurance Externality: an Economic Justification for Enterprise Liability*, 76 Cornell L Rev. 129, 161 (1990) (noting that the Coase Theorem is "well accepted"). That is, the market would favor products with the lowest sum of the cost of injuries plus the cost of injury prevention. *Id.*

Of course, real-world markets don't provide perfect consumer information. Manufacturers are able to "externalize" the injury costs of their products. Guido Calabresi, THE COSTS OF ACCIDENTS 70 (1970). That is, the manufacturer can force consumers, taxpayers, and society generally to subsidize his product by bearing part of the cost of the injuries it causes. This places the manufacturer who invests in safety at a competitive disadvantage, and unsafe products would tend to drive safer ones out of the marketplace. Product liability rules, by assessing risk retrospectively, compensate for imperfect consumer information. Steven P. Croley and Jon D. Hanson, *Rescuing the Revolution: The Revived Case for Enterprise Liability*, 91 Mich. L. Rev. 683, 707-08 (1993). See also W. Kip Viscusi, REFORMING PRODUCTS LIABILITY 66 (1991) ("The purpose of products liability is to fill the gaps left by market imperfections and to replicate the incentives that would have been generated had markets been functioning perfectly.")

In this way, "civil liability has a regulatory effect by promoting optimal deterrence – the taking of precautions and selection of activities that

minimize the sum of accident costs and accident avoidance costs." Kenneth S. Abraham, *The Insurance Effects of Regulation by Litigation*, in REGULATION THROUGH LITIGATION, at 212, 232 (W. Kip Viscusi ed. 2002). It is for the manufacturer to rationally decide whether it is cheaper to prevent future injuries by investing in safety precautions or to simply compensate future victims. *Id.*

Product liability duties therefore reflect a policy of making dangerous products pay their own way, that is, internalizing costs to achieve an efficient level of manufacturing operations. William M. Landes and Richard A. Posner, *The Positive Economic Theory of Tort Law*, 15 Ga. L. Rev. 851, 871-77 (1981); Richard C. Ausness, *Compensation For Smoking-Related Injuries: An Alternative to Strict Liability in Tort*, 46 Wayne L. Rev. 1085, 1140 (1990)("efficient allocation of resources is more likely if product prices reflect their actual social costs").

Viewed another way, the law requires the product's purchase price to reflect the costs of injuries so the "cheapest cost avoider" makes the most efficient allocation of resources. Guido Calabresi and Jon T. Hirschoff, *Toward a Test for Strict Liability in Torts*, Yale L.J. 1055, 1060 (1972) ("The question for the court reduces to a search for the cheapest cost avoider. . . . [i.e.] which of the parties to the accident is in the best position to make the cost-benefit analysis between accident costs and accident avoidance costs and to act on that decision once it is made."); *see also* Breyer, *supra*, at 175 (favoring rule "likely to place costs on the party best able to avoid them").

To the extent that preventing injury is cheaper than compensating the injured,

manufacturers have an economic incentive to make their products safer. *Id.* In this way, liability "is broadly consistent with an optimum investment in accident prevention by the enterprises subject to the standard." Richard A. Posner, *A Theory of Negligence*, 1 J. Legal Stud. 29, 30 (1972).

Safety by government regulation is a much different regime. It is premised on the belief that the marketplace cannot achieve the level of safety society demands. Croley and Hansen, *supra* at 736. Regulators therefore command manufacturers to do that which they would not do voluntarily. In many ways, regulation and liability are polar opposites. Administrative regulations are prospective; liability assesses past conduct. Regulations prescribe specific design or performance standards; a liability verdict assesses whether a manufacturer met a duty of care under the circumstances of a particular case. Regulatory penalties are imposed to enforce compliance; a liability verdict is measured to compensate for wrongful death and injury. *See* Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J. Legal Studies 357, 359 (1984) (explaining that administrative regulation is a centralized system of government control, while tort law is essentially a market-based system).

In his classic exposition, Judge Calabresi contrasts the indirect influence exerted on the market by tort law ("general deterrence") with governmental regulatory mandates ("specific deterrence"). Calabresi, THE COSTS OF ACCIDENTS, *supra*, at 68-129. As one scholar summarized:

> [U]nder a general deterrence regime, manufacturers, not government officials, make decisions about product safety. . . . In contrast,

> specific deterrence mandates a particular choice determined by the legislature or an administrative agency. *It is a raw exercise of state power.*

Richard C. Ausness, *Cigarette Company Liability: Preemption, Public Policy, and Alternative Compensation Systems*, 39 Syracuse L. Rev. 897, 927 (1988) (emphasis added). It is the exercise of government power, not the private decisions of individuals, that is preemption's concern.

For this reason, this Court has consistently held that preemption of direct regulation by administrative agencies does not necessarily include the indirect influence of tort awards:

> The effects of *direct* regulation on the operation of federal projects are significantly more intrusive than the *incidental* regulatory effects of such an additional award provision. . . . We believe Congress may reasonably determine that *incidental regulatory pressure is acceptable, whereas direct regulatory authority is not.*

*Goodyear Atomic Corp. v. Miller*, 486 U.S. 174, 185 (1988) (emphasis added). *See also English v. General Electric Co.*, 496 U.S. 72, 85 (1990) (The effect of tort awards "is neither direct nor substantial enough to place petitioner's claim in the preempted field" with administrative regulations); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 258 (1984) (vesting federal agency "with exclusive regulatory authority over the safety aspects of nuclear development" was not inconsistent with allowing plaintiffs to recover for injuries caused by nuclear hazards).

Justice Blackmun later described the import of these decisions: "The level of choice that a defendant retains in shaping its own behavior distinguishes the

indirect regulatory impact of the common law from positive enactments such as statutes and administrative regulations." *Cipollone, supra*, 505 U.S. at 536-37 (Blackmun, J., concurring in part, dissenting in part).

### B. Congress Would Not Have Intended To Ensure the Safety of the Most Potentially Dangerous Devices Through Regulation Alone.

As noted earlier, the Court of Appeals saw the PMA regime as

> an entirely new approach of ensuring consumer safety through increased federal regulation and oversight. It is thus much less clear that the continuation of the previous tort remedies in the PMA context is consistent with the MDA's purpose.

451 F.3d 123.

At the outset, it must be noted that the court's standard – whether tort remedies are consistent with the statute's purpose – may be appropriate for implied "conflict" preemption. *E.g.*, *Geier*, 529 U.S. at 873 (implied preemption where state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress"). However, a court's role in construing an express preemption provision is much more limited. The lower court's assertion is bereft of any authority indicating that Congress intended to abolish tort remedies and rely solely on FDA regulation.

The more appropriate starting place, as this Court has instructed, is the assumption that Congress was "familiar with common-law principles . . . recognized in ordinary tort litigation [and] 'likely

intended these common-law principles to obtain, absent specific provisions to the contrary.'" *Will v. Michigan Dept. of State Police*, 491 U.S. 58, 67 (1989), quoting *City of Newport v. Fact Concerts, Inc.*, 453 U.S. 247, 258 (1981).

One important common-law principle is that the two prongs of America's approach to product safety – regulation and liability – are complementary and not mutually exclusive. *See, e.g., CSX Transportation, Inc. v. Easterwood*, 507 U.S. 658, 668 (1993) (state "negligence liability could just as easily complement" railroad crossing regulations under the Federal Railroad Safety Act); *Silkwood* at 264 (Blackmun, J., dissenting) (Tort damages "complement the federal regulatory standards, and are an implicit part of the federal regulatory scheme."); *Larsen v. General Motors Corp.*, 391 F.2d 495, 506 (8th Cir. 1968) ("It is apparent that the National Traffic Safety Act is intended to be supplementary of and in addition to the common law of negligence and product liability."); *Graham v. Wyeth Labs.*, 666 F. Supp. 1483, 1493 (D. Kan. 1987) (state tort actions actually enhance the goal of the National Childhood Vaccine Injury Act of optimum vaccine safety).

As the former FDA Chief Counsel has written, "FDA product approval and state tort liability usually operate independently, each providing a significant, yet distinct level of consumer protection." Margaret J. Porter, *The Lohr Decision: FDA Perspective and Position*, 52 Food & Drug L.J. 7, 11 (1997). *See also* 1 American Law Institute, REPORTERS' STUDY: ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY, 50 (1991); Steven Shavell, *Liability for Harm Versus Regulation of Safety*, 13 J.

Legal Studies 357 (1984); Susan Rose-Ackerman, *Tort Law in the Regulatory State*, in TORT LAW AND THE PUBLIC INTEREST 82-83 (Peter H. Schuck ed., 1991).

Courts have described this complementary relationship by stating that federal regulatory standards are "a floor, not a ceiling." *See, e.g., Ferebee v. Chevron Chem. Co.*, 736 F.2d 1529, 1542-43 (D.C. Cir. 1984); *Dorsey v. Honda Motor Co.*, 655 F.2d 650, 656 (5th Cir. 1981); *see generally*, Clarence Morris, *The Role of Administrative Safety Measures in Negligence Actions*, 28 Tex. L. Rev. 143, 157-66 (1949).

> For a hundred years courts have considered axiomatic the common law principle that compliance with safety regulations is evidence for the jury that the defendant exercised due care. At the same time, such compliance generally 'does not prevent a finding of negligence where a reasonable man would take additional precautions.'

Paul Deuffert, *The Role of Regulatory Compliance in Tort Actions*, 26 Harv. J. on Legis. 175, 175 (1989), quoting Restatement (Second) of Torts § 288(C) (1965).[8]

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[8] See also Restatement (Third) of Torts: Product Liability § 4 (1998):

> (b) a product's compliance with an applicable product safety statute or administrative regulation is properly considered in determining whether the product is defective with respect to the risks sought to be reduced by the statute or regulation, but such compliance does not preclude as a matter of law a finding of product defect.

In enacting the MDA, Congress gave no indication of departing from that historical position. Certainly Congress was under no illusion that federal regulators are so effective that they need no assistance from common law liability.

Federal administrative agencies are subject to budgetary constraints, political pressures, and simple human shortcomings.[9]

> Federal administrative agencies have been subjected to an increasing barrage of criticism emanating from a variety of philosophical and political positions. Economists are concerned with the inefficiency, waste, and shortages they see caused by certain kinds of regulation. . . . Consumer groups complain that regulation is ineffective.

Stephen G. Breyer & Richard B. Stewart, ADMINISTRATIVE LAW AND REGULATORY POLICY 130-31 (2d ed. 1985). See also *See* 1 American Law Institute, REPORTERS' STUDY: ENTERPRISE RESPONSIBILITY FOR PERSONAL INJURY 47-49 (1991) (the consensus of empirical studies is that "although compliance with regulatory standards has exacted substantial costs from business, the payoff in injury prevention has been disappointingly modest.").

Certainly there is no support for the notion that Congress relied entirely upon the FDA's ability to ensure the safety of the large number of medical devices entering the marketplace. Adler and Mann,

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[9] It has been pointed out that the Titanic set sail in compliance with governmental regulations setting minimum requirements for lifeboats, though they could accommodate only about half the people on board. *Geier v. American Honda Motor Co., Inc.*, 529 U.S. 861, 903 n.19 (2000) (Stevens, J., dissenting).

*supra*, at 942. "To the contrary, Congress has repeatedly identified shortcomings in FDA's regulation of medical devices." *Id.* at n.191 (listing congressional investigative reports). Daniel W. Sigelman, *Turning the Tables on Drug Companies: Exposing Deficiencies in FDA Regulation*, 30 Trial 72 (1994) ("Implicit in the 'FDA approval defense' is the assumption that agency regulation protects the public from the dangers of marketed drugs. Congressional oversight of FDA's performance, however, challenges the validity of this assumption.").

One example stems from the Dalkon Shield scandal itself. The dishonesty of manufacturer A.H. Robins Co., its refusal to conduct adequate testing of its IUD, its disregard of adverse reports from physicians, and its destruction of evidence were not uncovered by the FDA. "To the contrary, the FDA turned its attention away from the Dalkon Shield after negotiating a 'voluntary' suspension of sales in the United States." Instead, that evidence was uncovered in the course of product liability litigation. Adler & Mann, *supra*, at 944.

As one court pointedly remarked, "It would have been inconsistent for the same Congress that enacted these sweeping reforms, intending to make a potentially dangerous industry safer for patients by blocking the admission of defective devices to the market, then to preempt product liability suits when those devices caused injury." *Goodlin*, *supra*, 167 F.3d at 1378.

Moreover, this Court has for more than two centuries held that "[o]ne of the first duties of government" is to safeguard "the right of every individual to claim the protection of the laws,

whenever he receives an injury." *Marbury v. Madison*, 5 U.S. (1 Cranch) 137, 163 (1803). Under the Due Process Clause, it is "the duty of every State to provide, in the administration of justice, for the redress of private wrongs." *Missouri Pacific Ry. Co. v. Humes*, 115 U.S. 512, 521 (1885). Indeed, the right to recover damages for wrongful personal injury is among the "absolute rights of individuals" that the Founders intended to guarantee to all Americans. *Ingraham v. Wright*, 430 U.S. 651, 675 (1977).

For Congress to have eliminated that right for those injured by unreasonably dangerous medical devices, without a mention of such a drastic step, would have been "spectacularly odd." *Lohr*, 518 U.S. at 491 (plurality opinion).

## CONCLUSION

For the above reasons, the decision of the court of appeals below should be reversed.

Respectfully submitted,

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August 27, 2007

No. 06-179

# In the Supreme Court of the United States

DONNA S. RIEGEL, INDIVIDUALLY AND AS ADMINISTRATOR OF THE ESTATE OF CHARLES R. RIEGEL,

*Petitioner*,

v.

MEDTRONIC, INC.,

*Respondent*.

**On Writ of Certiorari to the United States Court of Appeals for the Second Circuit**

## BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT


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## TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ..... iii

INTEREST OF THE *AMICUS CURIAE* ..... 1

STATEMENT ..... 1

A. The Medical Device Amendments And FDA's Clearance Of New Devices For Marketing ..... 2

B. The Preemption Clause And FDA's Regulation ..... 4

C. This Court's Decision In *Medtronic* v. *Lohr* ..... 4

D. The FDA's Current Views On The Scope And Importance Of Preemption With Respect To PMA Devices ..... 6

SUMMARY OF ARGUMENT ..... 7

ARGUMENT ..... 9

I. The Court Should Decline To Reexamine Petitioner's Arguments That Were Raised, And Properly Rejected, In *Lohr* ..... 9

II. Under The Framework Of Analysis Established In *Lohr*, Petitioner's Claims Are Expressly Preempted ..... 17

A. The Legislative History And FDA's Exemption Practice Confirm That The PMA Process Imposes "Requirements" That Are "Specific" ..... 19

## TABLE OF CONTENTS—Continued

**Page(s)**

B. The Legislative History and FDA's Exemption Practice Confirm That Petitioner's Claims Would Impose State-Law "Requirements" That Are "Specific" On the Evergreen Balloon Catheter ..... 23

III. The Court Should Reconsider The "Specificity" Gloss On 21 U.S.C. § 360k(a) ..... 26

CONCLUSION ..... 30

## TABLE OF AUTHORITIES

**Page(s)**

**Cases:**

*Arizona* v. *Rumsey*, 467 U.S. 203 (1984) ..... 8, 9, 26

*Bates* v. *Dow Agrosciences LLC*,
544 U.S. 431 (2005) ..... 10, 15

*Bourjaily* v. *United States*, 483 U.S. 171 (1987) ..... 16

*Buckman Co.* v. *Plaintiffs' Legal Comm.*,
531 U.S. 341 (2001) ..... *passim*

*Cipollone* v. *Liggett Group, Inc.*,
505 U.S. 504 (1992) ..... 10, 15

*Coastal Petroleum Co.* v. *American Cyanamid Co.*,
492 So. 2d 339 (Fla. 1986) ..... 12

*CSX Transp., Inc.* v. *Easterwood*,
507 U.S. 658 (1993) ..... 10, 15

*Eli Lilly & Co.* v. *Medtronic, Inc.*,
496 U.S. 661 (1990) ..... 16

*Hohn* v. *United States*, 524 U.S. 236 (1998) ..... 26

*Medtronic, Inc.* v. *Lohr*,
518 U.S. 470 (1996) ..... *passim*

*Monell* v. *New York City Dep't of Soc. Servs.*,
436 U.S. 658 (1978) ..... 26

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504 U.S. 374 (1992) ..... 9, 29

## TABLE OF AUTHORITIES—Continued

**Page(s)**

*Norfolk & W. Ry. Co.* v. *Train Dispatchers*, 499 U.S. 117 (1991) ..... 11

*Pilot Life Ins. Co.* v. *Dedeaux*, 481 U.S. 41 (1987) ..... 30

*San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236 (1959) ..... 11, 30

**Statutes and Regulations:**

7 U.S.C. § 136v(b) ..... 10, 15

15 U.S.C. § 1334(b) ..... 10, 15

21 U.S.C. § 331(e) ..... 19

21 U.S.C. § 351(B)(I) ..... 19

21 U.S.C. § 351(c) ..... 19

21 U.S.C. § 351(f)(1)(A)(I) ..... 19

21 U.S.C. § 351(f)(1)(B)(I) ..... 19

21 U.S.C. § 360c(a)(1)(A)(ii) ..... 2

21 U.S.C. § 360c(b)(1)(A) ..... 19

21 U.S.C. § 360c(c)(2)(A) ..... 19

21 U.S.C. § 360c(e)(1)(B) ..... 19

21 U.S.C. § 360c(f)(1) ..... 3

## TABLE OF AUTHORITIES—Continued


| | Page(s) |
|---|---|
| 21 U.S.C. § 360c(l) | 3 |
| 21 U.S.C. § 360e | 19 |
| 21 U.S.C. § 360e(a) | 3 |
| 21 U.S.C. § 360e(b) | 19 |
| 21 U.S.C. § 360e(c)(2) | 19 |
| 21 U.S.C. § 360e(d)(1)(A) | 3 |
| 21 U.S.C. § 360e(f) | 19 |
| 21 U.S.C. § 360h | 14 |
| 21 U.S.C. § 360k(a) | *passim* |
| 21 U.S.C. § 360k(b) | *passim* |
| 21 U.S.C. § 360(k)(2) | 19 |
| 21 U.S.C. § 382(a)(2)(A) | 19 |
| 49 U.S.C. App. § 1305(a)(1) | 30 |
| 49 U.S.C. § 20106 | 15 |
| 21 C.F.R. § 10.25(a) | 23 |
| 21 C.F.R. § 10.30 | 23 |
| 21 C.F.R. § 10.40(a)(2) | 23 |
| 21 C.F.R. § 801.437 | 22 |

## TABLE OF AUTHORITIES—Continued


**Page(s)**

21 C.F.R. § 808.1(d) ..... *passim*

21 C.F.R. § 808.1(d)(1) ..... *passim*

21 C.F.R. § 808.1(d)(3) ..... 26

21 C.F.R. § 808.51 (1999) ..... 25

21 C.F.R. § 808.52 (1999) ..... 25

21 C.F.R. § 808.55(b)(1) ..... 25, 29

21 C.F.R. § 808.55(b)(2) ..... 25, 29

21 C.F.R. § 808.94 (1999) ..... 25

21 C.F.R. § 814.39 ..... 3

21 C.F.R. § 814.80 ..... 3

21 C.F.R. § 897.1 *et seq.* (1997) ..... 22

ALABAMA CODE § 13A-12-3 (2007) ..... 25

ARIZ. REV. STAT. ANN. §§ 12-681 to 12-686 (1992) ..... 11

21 CAL. HEALTH & SAFETY CODE § 26463(m) (1984) .... 28

21 CAL. HEALTH & SAFETY CODE § 26614 (1984) ..... 24

21 CAL. HEALTH & SAFETY CODE § 26615 (1984) ..... 24

21 CAL. HEALTH & SAFETY CODE § 26618 (1984) ..... 24

21 CAL. HEALTH & SAFETY CODE § 26631 (1984) ..... 24

## TABLE OF AUTHORITIES—Continued

Page(s)

21 CAL. HEALTH & SAFETY CODE § 26640 (1984) ..... 24

21 CAL. HEALTH & SAFETY CODE § 26641 (1984) ..... 24

CONN. GEN. STAT. §§ 52-572m to 52-572q (2004) ..... 11

FLA. STAT. ANN. § 2.01 (1985) ..... 12

IND. CODE ANN. § 33-1-1.5-1 to 33-1-1.5-10 (West 1983 & Supp. 1996) ..... 11

LA. REV. STAT. ANN. §§ 9:2800.51 to 9:2800.59 (West 1991) ..... 11

ME. REV. STAT. ANN. tit. 14 (West 1980) ..... 11

S.C. CODE ANN. § 15-73-10 (Law. Co-op. 1993) ..... 11

TEX. CIV. PRAC. & REM. CODE § 82.001 *et seq.* (Vernon 1997) ..... 12

**Miscellaneous:**

Bernstein, *The New-Tort Centrifuge*, 49 DEPAUL L. REV. 413 (1999) ..... 12

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**TABLE OF AUTHORITIES—Continued**

**Page(s)**

42 Fed. Reg. 30383 (1977) ..... 27, 29

42 Fed. Reg. 9186 (1977) ..... 28

43 Fed. Reg. 18661 (1978) ..... *passim*

44 Fed. Reg. 19438 (1979) ..... 20, 28

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62 Fed. Reg. 63271 (1997) ..... 22, 25

63 Fed. Reg. 50660 (1998) ..... 22

H.R. 11124, 94th Cong., 2d Sess. (1976) ..... 21

H.R. Conf. Rep. 94-1090 (1976) ..... 21

H.R. Rep. No. 94-853 (1976) ..... 2, 4, 20

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S. Rep. No. 94-33 (1975) ..... 21

Starr, "Preface," in FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS (AEI eds. R. Epstein and M. Greve 2007) ..... 17

## BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENTS

## INTEREST OF THE *AMICUS CURIAE*[1]

The Chamber of Commerce of the United States of America (the Chamber) is the world's largest business federation. The Chamber represents an underlying membership of more than three million companies and professional organizations of every size, in every industry, and from every region of the country. An important function of the Chamber is to represent its members' interests in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files *amicus curiae* briefs in cases that raise issues of vital concern to the Nation's business community.

This is such a case. The Chamber's members include device manufacturers that depend on preemption under the Medical Device Amendments, 21 U.S.C. § 360k(a), as protection against the imposition by state and local governments of burdensome, divergent and even conflicting requirements relating to premarket-approved devices. The Chamber's membership also includes millions of businesses that are subject to the many other statutory schemes and regulations that preempt state and local laws. Accordingly, the Chamber and its members have a substantial interest in ensuring that this Court properly resolves the significant issues raised in this case.

## STATEMENT

This case presents important questions about the scope of express preemption under the Medical Device Amendments to

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[1] The parties' letters of consent to the filing of this brief have been filed with the Clerk. Under Rule 37.6 of the Rules of the Court, *amicus curiae* states that no counsel for a party has written this brief in whole or in part and that no person or entity, other than the *amicus curiae*, its members, or its counsel, has made a monetary contribution to the preparation or submission of this brief.

the Food, Drug and Cosmetic Act, 21 U.S.C. § 360k(a). Specifically, the Court is called upon to decide whether, under the framework of analysis set forth in *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470 (1996), Section 360k(a) preempts divergent requirements imposed by state tort law on the design, manufacture, and labeling of a medical device that has "run[] the gauntlet" (518 U.S. at 494) of obtaining premarket approval (PMA) from the Food and Drug Administration (FDA). Like the Second Circuit in this case, the vast "majority of circuits addressing this question" (Pet. App. 2a; *id.* at 23a) have upheld preemption in this setting. So should this Court.

## A. The Medical Device Amendments And FDA's Clearance Of New Devices For Marketing

Enacted in 1976, the Medical Device Amendments (MDA) vastly expanded the authority of the FDA to regulate medical devices "to assure the[ir] safety and effectiveness." H.R. Rep. No. 94-853, at 3 (1976). At the same time that it established a comprehensive regulatory regime at the federal level, Congress sought to protect innovations in device technology from being "stifled by unnecessary restrictions." *Id.* at 12; see also *ibid.* (describing MDA as "a balanced regulatory proposal"). Toward the latter end, Congress sought to shield device manufacturers from the "undu[e] burden[]" imposed by differing state laws and regulation by including a preemption provision that contains a "general prohibition on non-Federal regulation." *Id.* at 45.

The MDA classifies medical devices into three categories based on the potential risks of harm. See Pet. App. 7a-9a; *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 U.S. 341, 344 (2001). Devices carrying the highest risks, so-called "Class III" devices, are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health," or that "present[] a potential unreasonable risk of illness or injury." 21 U.S.C. § 360c(a)(1)(A)(ii). All post-1976 devices, including the Evergreen Balloon Catheter at issue in this case, initially are automatically considered Class III devices and cannot be

marketed without FDA clearance or approval. *Id.* §§ 360e(a), 360c(f)(1).

Premarket clearance can occur in either of two ways. *First*, FDA evaluates some Class III devices under the PMA process. Characterized by this Court as "exhaustive" (*Buckman*, 531 U.S. at 349) and "running the gauntlet" (*Lohr*, 518 U.S. at 494), the PMA process is the FDA's most stringent form of regulatory review. It "involves a time-consuming inquiry into the risks and efficacy of each device." *Buckman*, 531 U.S. at 348. Only a tiny fraction of new Class III devices go through the PMA process. See Pet. App. 13a (only 32 out of 3180 devices in fiscal year 2005); see also *id.* at 3a (explaining that Second Circuit's decision affects only a "small universe of cases").

The *second* method of obtaining FDA clearance to market new Class III devices is through the so-called "510(k) process." Aimed at fostering competition, the 510(k) process allows a device to bypass the stringent PMA requirements if it is "substantially equivalent" to a "grandfathered" device on the market before passage of the MDA in 1976. See 21 U.S.C. § 360c(l); *Lohr*, 518 U.S. at 494. The 510(k) process "lacks the PMA review's rigor" (*Buckman*, 531 U.S. at 348) and focuses on "*equivalence*, not safety." *Lohr*, 518 U.S. at 493 (internal quotations omitted). "[I]n contrast to the 1,200 hours necessary to complete a PMA review, the § 510(k) review is completed in an average of only 20 hours." *Id.* at 479.

At the conclusion of the PMA process, FDA issues a final order approving the device for marketing if the manufacturer has demonstrated that the device's safety and effectiveness is reasonably assured. 21 U.S.C. § 360e(d)(1)(A). Such an order authorizes marketing the device with the particular labeling (including product warnings) and according to the specific design and manufacturing processes submitted to FDA. The order prohibits changes to the approved labeling, product design, manufacturing process, or construction of the device that would affect its safety or effectiveness without FDA approval. 21 C.F.R. §§ 814.39, 814.80; Pet. App. 9a-10a.

## B. The Preemption Clause And FDA's Regulation

In passing the MDA, Congress took steps to preserve the uniformity of the new federal regulatory scheme as well as to protect innovations in device technology from being "stifled by unnecessary restrictions" imposed by state and local governments. H.R. Rep. No. 94-853, at 12, 45 (1976). Specifically, Congress included the following preemption provision:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use *any* requirement –
>
> (1) which is different from, or in addition to, *any* requirement applicable under this chapter to the device, and
>
> (2) which relates to the safety or effectiveness of the device *or to any other matter included in a requirement* applicable to the device under this chapter.

21 U.S.C. § 360k(a) (emphasis added). The only exception to this sweeping command is for state requirements that the FDA elects to exempt from preemption under 21 U.S.C. § 360k(b).

The FDA has issued a regulation interpreting the MDA's preemption clause, 21 C.F.R. § 808.1(d), which provides that "[s]tate or local requirements are preempted only when the [FDA] has established specific counterpart regulations or there are other specific requirements applicable to a particular device." The regulation also states that Section 360k(a) "does not preempt State or local requirements of general applicability." *Id.* § 808.1(d)(1).

## C. This Court's Decision In *Medtronic* v. *Lohr*

This Court interpreted the MDA's preemption clause and FDA's regulation in *Lohr*. The case involved a "grandfathered" medical device that had been cleared through the 510(k) process, which involves only a "limited form of review" by FDA. 518 U.S. at 478. This Court took pains to contrast the 510(k) process

with the far more "rigorous" PMA process. 518 U.S. at 477-78; see also *id.* at 479, 494.

Three separate opinions combined to resolve the issues before the Court in *Lohr*. Five Members of the Court concluded, as a threshold matter, that Section 360k(a)'s reference to state "requirements" includes requirements imposed under the common law.[2] The Court unanimously held that claims embodying state requirements that are *identical* to applicable federal requirements are not preempted by the MDA; and a 5-4 majority ruled that the Lohrs' manufacturing and warning claims also were not preempted. The Court also held that, because the 510(k) process does not impose *any* federal design "requirements," it does not preempt state design claims. 518 U.S. at 492-94; *id.* at 513 (O'Connor, J.). Justice Breyer cast the deciding vote with respect to Section 360k(a)'s coverage of common-law requirements and the non-preemption of the Lohrs' manufacturing and warning claims.

The Court's 5-4 holding that the manufacturing and warning claims were not preempted turned on the *general applicability* of the federal regulations imposing manufacturing and labeling requirements – regulations that apply not just to a single medical device or class of devices but to virtually all devices. In this connection, both Justice Stevens's opinion and Justice Breyer's concurrence relied on the FDA's regulation interpreting Section 360k(a) as preempting "[s]tate or local requirements * * * only when the [FDA] has established *specific* counterpart regulations or there are other *specific* requirements applicable to a particular device." 21 C.F.R. § 808.1(d) (emphasis added).[3] The focus of

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[2] See 518 U.S. at 511 (O'Connor, J., joined by Rehnquist, C.J., and by Scalia and Thomas, JJ., concurring in part and dissenting in part) ("If § 360k(a)'s language is given its ordinary meaning, it *clearly* pre-empts any state common-law action that would impose a requirement different from, or in addition to, that applicable under the FDCA * * * .") (emphasis added); *id.* at 504-505 (opinion of Breyer, J.) (same).

[3] See 518 U.S. at 495 (Stevens, J.) ("our interpretation of the pre-emption

Justice Breyer's tie-breaking concurring opinion was on the pertinent *federal* (as opposed to the *state*) requirements. 518 U.S. at 507 (Breyer, J.) ("Insofar as there are any applicable *FDA requirements* here, those requirements, even if numerous, *are not 'specific' in any relevant sense.*") (emphasis added); *ibid.* ("[N]o law forces the FDA to make *its requirements* pre-emptive if it does not think it appropriate.") (emphasis added).

### D. The FDA's Current Views On The Scope And Importance Of Preemption With Respect To PMA Devices

As the Solicitor General's brief at the petition stage explains (at 17), the FDA interprets Section 360k(a) as expressly pre-empting state tort claims that seek to impose different or additional requirements on devices that have won premarket approval. More specifically, FDA takes the view that "the agency's approval" of a device "through the PMA process does impose specific requirements for the product, including requirements for its design, manufacturing, performance, labeling, and use." U.S. Br. at *14, *Horn* v. *Thoratec Corp.*, No. 02-4597, 2004 WL 1143720 (filed May 14, 2004) ("U.S. *Horn* Br."). Building on the holding of a majority in *Lohr* "that state tort law judgments do impose a requirement for purposes of preemption under the MDA," the FDA also interprets Section 360k(a) as preempting "the application by a court of a general common law duty to a specific device." *Id.* at *18.

Equally important, the FDA has explained that "strong public policy considerations" support the agency's interpretation

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statute is *substantially informed* by [FDA's] regulations") (emphasis added); *id.* at 496 (there is a "sound basis" for giving "substantial weight to the agency's view of the statute"); *id.* at 505-06 (Breyer, J.) (it "makes sense" to infer that FDA "possesses a degree of leeway to determine which rules, regulations, or other administrative actions will have pre-emptive effect"). The majority's reliance on the "specificity" concept was somewhat equivocal, however. It elsewhere stated: "[W]e do not believe that th[e] statutory and regulatory language necessarily precludes 'general' federal requirements from ever pre-empting state requirements, or 'general' state requirements from ever being pre-empted." *Id.* at 500.

of Section 360k(a) as preempting divergent state tort requirements in this setting. *Id.* at *25. Such "[s]tate common law tort actions," the agency has explained, can "threaten the statutory framework for the regulation of medical devices, particularly with regard to FDA's review and approval of product labeling," by allowing "lay judges and juries to second-guess" the scientific judgments made by expert regulators at FDA. *Ibid.* State tort litigation can also cause other detrimental effects that "harm the public health," including the proliferation of "scientifically unsubstantiated warnings," "underutilization of beneficial treatments" by physicians and patients, and even "withdrawal of FDA-approved products from the market in conflict with the agency's expert determination that such products are safe and effective." *Id.* at *26. Thus, FDA recognizes that the MDA's express preemption clause furthers not only Congress's goal of protecting innovation and reducing regulatory burdens but also its goal of protecting and promoting the public health.

## SUMMARY OF ARGUMENT

I. A substantial number of the arguments pressed by petitioner and her supporting *amici* in this case were also advanced and refuted by the parties – and explicitly or implicitly rejected by this Court – in *Medtronic* v. *Lohr*. Petitioner's recycled arguments relating to the text, legislative history, and "purpose" of the Medical Device Amendments, and to the pre-1976 history of tort litigation involving medical devices, all target the conclusion of a majority of this Court in *Lohr* that Section 360k(a)'s reference to state "requirement[s]" includes requirements imposed under the common law. That holding is eminently correct, and is supported by a long line of this Court's decisions construing identical or very similar language in other preemption clauses and recognizing the clear regulatory effect of tort law. Indeed, it would be anomalous – and lead to an irrational and unmanageable patchwork of preemption that Congress could not have intended – to read the MDA's preemption clause as excluding requirements that happen to be based in state common law, because many States have codified their

common law of torts in whole or in part. Although petitioner and her *amici* effectively ask this Court to overrule this aspect of *Lohr*, they come nowhere close to providing the requisite "special justification" needed to overcome *stare decisis* concerns. *Arizona* v. *Rumsey*, 467 U.S. 203, 212 (1984). In fact, all of petitioner's recycled arguments lack merit and were properly rejected in *Lohr*.

II. Under the framework of analysis established in *Lohr*, petitioner's claims are expressly preempted. The PMA process imposes specific federal requirements relating to design, manufacturing, and labeling on an approved device within the meaning of 21 U.S.C. § 360k(a) and 21 C.F.R. § 808.1(d). Petitioner's state-law claims seek to impose different or additional counterpart requirements on the Evergreen Balloon Catheter. Moreover, there is substantial evidence in both (1) the legislative history of the MDA, and (2) the FDA's practice of administering exemptions from preemption under 21 U.S.C. § 360k(b), to confirm the Second Circuit's determination that the *Lohr* framework and FDA's regulation necessitate preemption in this setting. See pages 19-26, *infra*.

III. If the Court nevertheless concludes that petitioner's claims are not preempted under the *Lohr* framework, then it should take this occasion to reexamine the FDA's "specificity" gloss on Section 360k(a) that was endorsed in *Lohr* (albeit equivocally; see note 3, *supra*). As a careful examination of the FDA's regulatory notices makes clear, the agency never intended to impose a limit on the *type* of federal requirement that triggers preemption under the MDA. Instead, 21 C.F.R. § 808.1(d)'s reference to "specific FDA requirements applicable to a particular device or class of devices" was intended to make clear that some federal requirement *must actually be in place* (not merely be capable of being put in place) before counterpart state requirements are preempted. The four dissenting Justices in *Lohr* were correct in observing that "[t]he statute makes no mention of a requirement of specificity" (518 U.S. at 512 (O'Connor, J.)), and indeed Section 360k(a) broadly provides

that "any requirement applicable under this chapter" to a device triggers preemption of counterpart state requirements.

As for the FDA's suggestion that Section 360k(a) does not preempt state and local requirements "of general applicability" (21 C.F.R. § 808.1(d)(1)), that interpretation is contrary to the text of the preemption clause (as the Solicitor General recognized in *Lohr*) as well as refuted by the FDA's own exemption practice. The Court's decision to rely on this narrowing interpretation in *Lohr* rested on a misunderstanding of the FDA's prior exemption practice. For all of these reasons, and because a similar "specificity" gloss has been rejected as "irrational" by this Court in other preemption settings (*Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374, 386 (1992)), the Court should revisit and overrule its endorsement in *Lohr* of a "specificity" gloss on the broad text of Section 360k(a).

## ARGUMENT

### I. The Court Should Decline To Reexamine Petitioner's Arguments That Were Raised, And Properly Rejected, In *Lohr*

To read petitioner's opening brief and the briefs of her supporting *amici*, one would never guess that a majority of this Court in *Lohr* concluded that state tort duties imposed through the common law constitute "requirements" within the meaning of 21 U.S.C. § 360k(a). See Pet. App. 20a-21a, 30a-31a; note 2, *supra*. As it turns out, a substantial number of the arguments advanced by petitioner and her *amici* were made and refuted by the parties – and rejected either explicitly or implicitly by this Court – in *Lohr*. Because petitioner and her *amici* offer no reason why these arguments have improved with age and should now be revisited – much less the "special justification" required to overcome *stare decisis* concerns (*Arizona* v. *Rumsey*, 467 U.S. 203, 212 (1984)) – all of these recycled arguments should be rejected out of hand.

A. In *Lohr*, five Members of this Court concluded that Congress's express preemption of "any [state] requirement" that

is "different from, or in addition to," a federal requirement applicable to a medical device (21 U.S.C. § 360k(a)) encompasses requirements imposed through the common law of torts. Nevertheless, petitioner contends in a footnote that "[t]he majority holding in *Lohr* does not resolve the question whether damages claims can ever be considered 'requirements' under § 360k(a)." Pet. Br. 16 n.5; accord Br. of Consumers Union ("CU Br."), at 13 (same). Although petitioner does not provide any citation for this assertion, she no doubt is referring to the statement in Section VI of Justice Stevens's opinion declining to resolve this issue. That portion of the opinion, however, garnered only four votes. See 518 U.S. at 508 (Breyer, J.) ("I do not join Part VI, because I am not convinced that future incidents of MDA pre-emption of common-law claims will be 'few' or 'rare[.]'"). Indeed, Justice Breyer even gave as an example of a claim that *would* be preempted by the MDA "a state-law tort action that premises liability upon the defendant manufacturer's failure to use a 1-inch wire," where "a federal MDA regulation requires a 2-inch wire." *Id.* at 504.

Even if this issue remained open, there is no good reason to resolve it in petitioner's favor – and many reasons to adhere to the Court's ruling in *Lohr*. In a line of cases involving other preemption clauses that nullify state "requirements," this Court has repeatedly held that the term encompasses requirements imposed by state tort or common law. See, *e.g.*, *Cipollone* v. *Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (involving Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1334(b)); *Bates* v. *Dow Agrosciences LLC*, 544 U.S. 431, 443 (2005) (involving Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 136v(b)); see also *CSX Transp., Inc.* v. *Easterwood*, 507 U.S. 658, 662 (1993) (reaching same conclusion as to Federal Railroad Safety Act's preemption of certain state "law[s], rule[s], regulation[s], order[s], or standard[s] relating to railroad safety"). These decisions are controlling here.

Beyond that, this Court's decisions in *Cipollone*, *Medtronic*, *Bates*, and *Easterwood* all build on older decisions that rely on

the same principle or acknowledge the clear regulatory effect of common-law judgments. In *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236 (1959), for example, this Court observed that "[state] regulation can be as effectively exerted through an award of damages as through some form of preventive relief. The obligation to pay compensation can be, indeed is designed to be, a potent method of governing conduct and controlling policy." *Id.* at 247. Similarly, in *Norfolk & W. Ry. Co.* v. *Train Dispatchers*, 499 U.S. 117 (1991), the Court held that the phrase "all other law, including State and municipal law" simply "does not admit of [a] distinction * * * between positive enactments and common-law rules of liability." *Id.* at 128.

B. In light of the powerful regulatory function of tort litigation today, it would be anomalous to read the MDA's preemption clause as excluding requirements that happen to be founded upon state common law. But there at least are four additional reasons why that result is nonsensical and would lead to absurd results.

*First*, many States have codified their common-law tort regimes. See, *e.g.*, ARIZ. REV. STAT. ANN. §§ 12-681 to -686 (1992); CONN. GEN. STAT. §§ 52-572m to 52-572q (2004); IND. CODE ANN. § 33-1-1.5-1 to 33-1-1.5-10 (West 1983 & Supp. 1996); LA. REV. STAT. ANN. §§ 9:2800.51 to 9:2800.59 (West 1991). See generally Hermann & Ritts, *Preemption and Medical Devices: A Response to Adler and Mann*, 51 FOOD & DRUG L.J. 1, 9 n.41 (1996) (collecting other statutes). Under petitioner's view, tort requirements in these jurisdictions would be pre-empted but identical common-law requirements in neighboring States would not. Why should such an absurd design be attributed to Congress?[4]

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[4] Notably, these codifications are not just a recent phenomenon. South Carolina, for example, adopted a product liability statute in 1962, and Maine followed suit in 1973. See S.C. CODE ANN. § 15-73-10 (Law. Co-op. 1993) (adopted 1962); ME. REV. STAT. ANN. tit. 14, § 221 (West 1980) (adopted 1973). Thus, at the time Congress enacted the MDA in 1976, this patchwork was already in existence.

*Second*, some States that have not enacted comprehensive product liability or tort statutes have nonetheless passed more limited tort reform measures. See, *e.g.*, TEX. CIV. PRAC. & REM. CODE § 82.001 *et seq.* (Vernon 1997); Comment, *The Products Liability Act of 1993: How It Changes Texas Law*, 45 BAYLOR L. REV. 633, 635 (Summer 1993). As a result of such measures, tort claims in these States are based on a hybrid of common law and positive law. Given the hybrid nature of tort law in many jurisdictions, it would be unmanageable – and require a time-consuming threshold judicial inquiry into state tort law – for preemption to turn on whether a requirement is rooted in a statute as opposed to the common law.

*Third*, the common law of many States originated in early *statutes* or *constitutional provisions* adopting the English common law wholesale as the law of the State. For example, "[i]n 1819, the territorial legislature of Florida adopted a statute declaring the common law of England to be of force in Florida. The statute * * * is still in effect * * * ." *Coastal Petroleum Co.* v. *American Cyanamid Co.*, 492 So. 2d 339, 347 (Fla. 1986) (Boyd, J., dissenting) (discussing FLA. STAT. ANN. § 2.01 (1985)); see also Bradley & Goldsmith, *Customary International Law As Federal Common Law: A Critique of the Modern Position*, 110 HARV. L. REV. 815, 870 n.345 (1997) ("[M]ost states have receiving statutes that incorporate as rules of decision at least part of the common law of England."). Since state common-law doctrines evolved from these early English sources, whose legitimacy and force are in turn contingent upon provisions of state *positive* law, it makes little sense to treat common-law requirements as qualitatively different from statutory requirements.

*Fourth*, reliance on a distinction between common-law and statutory requirements is especially odd in the area of tort law, where "[c]ompendia such as the torts Restatements help to blur the line between statutes and case law." Bernstein, *The New-Tort Centrifuge*, 49 DEPAUL L. REV. 413, 426 (1999). For all of these reasons, it makes no sense to read into Section 360k(a) an

exception for state requirements that happen to be rooted in the common law. That argument was properly rejected in *Lohr*.

C. Petitioner nevertheless maintains (at 15, 19-20) that the state "requirements" referred to in Section 360k(a) should be understood to exclude common law requirements because (1) the "federal 'requirements'" referenced in Section 360k(a) "flow solely from positive law – the MDA and it regulations"; and (2) the exemption provision, 21 U.S.C. § 360k(b), also refers to "requirements" but logically cannot include common law requirements. Both of these arguments were advanced in *Lohr*. See Nos. 95-754, 95-886 Br. for Cross-Pet. Lohrs, at 11-12, 18, 24-25; Nos. 95-754, 95-886 Reply Br. Cross-Pet. Lohrs, at 8-9. Both were refuted by Medtronic and by the Solicitor General. See, *e.g.*, Nos. 95-754, 95-886 Br. for Cross-Resp. Medtronic, at 12-13, 16-17. For example, the Solicitor General explained:

> The problem with [the Lohrs'] reasoning is that the limitation on the type of federal provisions that have preemptive effect is not attributable to the term "requirement." It is, instead, attributable to the words that modify "requirement." A state provision may be preempted only by a federal requirement "applicable under this chapter." 21 U.S.C. 360k(a). It is the latter phrase that limits the federal provisions having preemptive force to those imposed by the FDCA and implementing regulations, rather than by common law.

Nos. 95-754, 95-886 U.S. Br. 16-17; see also *id.* at 18-19 (refuting argument that the exemption provision, Section 360k(b), excludes common law requirements).

D. Next, petitioner and her *amici* argue that state common law requirements fall outside of Section 360k(a) because "general common-law duties are not requirements 'with respect to a device.'" Pet. Br. 15 (quoting § 360k(a)); accord AARP Br. 4; AAJ Br. 2-3, 10-11. The same argument was raised in *Lohr*. See Nos. 95-754, 95-886 Br. for Cross-Pet. Lohrs, at 12, 19-21; Nos. 95-754, 95-886 Reply Br. Cross-Pet. Lohrs, at 5-7. And it

was refuted by Medtronic and the Solicitor General. See, *e.g.*, Nos. 95-754, 95-886 Br. for Cross-Resp. Medtronic, at 13-15. As the Solicitor General correctly observed, the argument is "strained as a grammatical matter":

> Section [360k(a)] provides in relevant part that no State "may establish or continue in effect *with respect to a device intended for human use* any requirement * * * which is different from [a federal requirement]" * * *. The Lohrs read the italicized phrase as modifying "requirement" * * *. But the "with respect to" phrase cannot modify the word "requirement," because "requirement" comes *after* that phrase. Rather, the phrase modifies the words ("establish or continue in effect") that come immediately *before* it. * * * The phrase * * * preserves the authority of a State to have [a] requirement in effect insofar as it applies to things *other than* medical devices. By allowing in this manner for partial preemption of state "requirement[s]," the "with respect to" clause suggests that such a requirement *may be one of general applicability*.

Nos. 95-754, 95-886 U.S. Br. 17-18 (emphasis altered).

E. In a final textual argument, petitioner and her *amici* also point to 21 U.S.C. § 360h, which they describe as a "savings clause" demonstrating that "Congress expected that state-law claims would proceed against device manufacturers." Pet. Br. 13; see also *id.* at 20-21; CU Br. 17. Here again, this argument was raised and soundly refuted in *Lohr* (so much so that none of the *Lohr* opinions even mentions this provision). Compare Nos. 95-754, 95-886 Br. for Cross-Pet. Lohrs, at 12, 27-28 and Nos. 95-754, 95-886 Reply Br. Cross-Pet. Lohrs, at 10 with Nos. 95-754, 95-886 Br. for Cross-Resp. Medtronic, at 17-18 (explaining that Section 360h has to do only with compliance with certain administrative orders issued by FDA and its "reference to * * * liability is not necessarily a reference to personal injury tort claims" as opposed to contractual liability). Even if the provision does refer to tort liability, it would show only that Congress expected that *some* tort claims would not be preempted

by Section 360k(a) – a point independently established by *Lohr* as well as by the MDA's exemption provision.

F. Finally, petitioner and her *amici* advance a hodgepodge of additional arguments based on the legislative history of the MDA, the history of tort litigation involving devices, and the statutory "purpose" of protecting consumers. See Pet. Br. 15-18;AAJ Br. 2; CU Br. 7-10; AARP Br. 2; see also Pet. App. 45a (Pooler, J., concurring in part and dissenting in part) (similarly invoking legislative history). These arguments, they suggest, show that Congress could not possibly have intended to include common law "requirements" in Section 360k(a).

Every one of these arguments was raised in *Lohr*. See Nos. 95-754, 95-886 Br. for Cross-Pet. Lohrs, at 28-34; Nos. 95-754, 95-886 Br. for Resp. Lohrs, at 37-41. Every one was implicitly rejected by the five Justices who concluded that Section 360k(a)'s reference to "requirements" includes requirements imposed by state common law. Petitioner has offered no new or persuasive reason – none – why this Court should revisit this holding in *Lohr*.

In any event, these arguments are all unavailing. For starters, petitioner is simply wrong to suggest that "[i]n 1976, for Congress to have preempted damages claims without providing an alternative means of compensation would have been unprecedented." Pet. Br. 18. In fact, Congress did just that in 1969 when it amended the Federal Cigarette Labeling and Advertising Act, 15 U.S.C. § 1334(b) (see *Cipollone*, *supra*); in 1970 when it passed the Federal Railroad Safety Act, 49 U.S.C. § 20106 (see *Easterwood*, *supra*); and again in 1972 when it amended the Federal Insecticide, Fungicide and Rodenticide Act, 7 U.S.C. § 136v(b) (see *Bates*, *supra*). It is thus hardly unprecedented (or even surprising) that Congress would use the same term – "requirement" – to preempt common law requirements in 1976 when it passed the MDA.

Equally unavailing are the arguments based on the MDA's legislative history and "purpose" and on the history of tort

litigation involving devices.[5] The last argument overlooks the seismic changes in the American law of product liability that occurred beginning in the 1960s, not long before Congress amended the MDA. To the extent Congress in 1976 acted against a backdrop of tort litigation, it was tort litigation that looked vastly different from the tort litigation of today. See generally No. 05-1342 Br. of the Chamber of Commerce of the United States, *Watters* v. *Wachovia Bank, N.A.*, at 18-20.

Finally, petitioner's argument based on the statutory "purpose" of protecting consumers and furthering the public health ignores the possibility – which FDA itself has recognized (see pages 6-7, *supra*) – that state tort litigation can *undermine* the public health in a variety of ways (by causing overwarning, spurring manufacturers to provide warnings that FDA has rejected as scientifically unfounded, discouraging beneficial uses of devices, and impeding innovation). The argument also assumes incorrectly that Congress's purpose in passing the MDA was unitary. In fact, Congress enacted a "balanced regulatory proposal" that sought *not only* to protect consumers from unsafe and ineffective devices (principally by conferring new authority on the FDA) *but also* to encourage device innovation and reduce the burdens on interstate commerce. See pages 2, 4, *supra*. As the Second Circuit correctly observed, "a finding of preemption is consistent with" the latter purposes. Pet. App. 34a.[6]

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[5] This Court has routinely refused to take the "extraordinary" step of "requir[ing] legislative history to confirm the plain meaning of" a statute. *Bourjaily* v. *United States*, 483 U.S. 171, 178 (1987). See also *Eli Lilly & Co.* v. *Medtronic, Inc.*, 496 U.S. 661, 669 n. 2 (1990) (statute can have effects not explicitly mentioned in its legislative history).

[6] Petitioner and various *amici* repeatedly invoke the so-called "presumption against preemption" in urging this Court to reject the preemption defense in this case. See Pet. Br. 13, 21; Brief of Public Health Advocacy Institute ("PHAI Br."), at 2-16. The short answer to this argument is that the presumption is *already* reflected in the framework adopted in *Lohr* for analyzing express preemption. Several of petitioner's *amici* also invoke a report authored in 1991 by then-Judge

## II. Under The Framework Of Analysis Established In *Lohr*, Petitioner's Claims Are Expressly Preempted

Once petitioner's recycled arguments are set to one side, this case is easily resolved in respondent's favor under the *Lohr* framework. By its plain terms, Section 360k(a) preempts "any" state "requirement" that is "different from, or in addition to" a counterpart federal requirement that applies to a medical device, so long as the state requirement (1) "relates" either "to the safety or effectiveness of the device or to any other matter included in" a federal requirement, and (2) has not been exempted from preemption by FDA. 21 U.S.C. § 360k(a). In *Lohr*, a majority held that judgments in state tort suits qualify as state "requirements" covered by Section 360k(a). See Pet. App. 20a-21a. Relying on 21 C.F.R. § 808.1(d), a different majority in *Lohr* also suggested that, for federal requirements to trigger preemption under Section 360k(a), they must be "specific" to a device or class of devices. Pet. App.18a-19a.[7]

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Kenneth Starr that expresses concern about the doctrine of implied "obstacle" preemption. See PHAI Br. 4, 14-15; AAJ Br. 9 n.3. This case, however, involves express preemption. In any event, Dean Starr's views about the doctrine of preemption have changed in recent years in response to fundamental changes in the legal landscape. See Starr, "Preface," in FEDERAL PREEMPTION: STATES' POWERS, NATIONAL INTERESTS, at xv (AEI eds. R. Epstein and M. Greve 2007).

[7] The concept of "specificity" is ambiguous. A requirement can be "specific" in *content* (as in Justice Breyer's example in *Lohr* of a 2-inch wire requirement, which is specific when compared to a more generalized duty to use reasonable care in the design of a product). Alternatively, a requirement can be "specific" in *applicability* (as where it applies to a single device or class of devices). FDA's regulation makes clear, however, that it is the *latter* gloss that the agency intends for the state "requirements" covered by Section 360k(a). See 21 C.F.R. § 808.1(d)(1) (Section 360k(a) "does not preempt State or local requirements of general *applicability*") (emphasis added). At the same time, *Lohr* makes clear that common law duties that apply generally even to products other than devices may become "specific" where, as here, they are applied to a particular medical device in the course of litigation.

In *Lohr*, the Court held that certain federal labeling and good manufacturing practices (GMP) requirements, which applied generally to *all* medical devices, were not sufficiently "specific" to trigger preemption. Those regulations are distinguishable from the regulations governing the PMA process because the former apply, "with a few limited exceptions," to "every medical device." 518 U.S. at 497. In contrast, FDA's requirements relating to the PMA process – even viewed in the abstract, apart from their specific application to the Evergreen Balloon Catheter – are limited to a *single regulatory class* of medical devices: devices for which premarket approval is sought. The FDA has acknowledged that "specific FDA requirements applicable to a particular device *or class of devices*" trigger express preemption under the MDA. 43 Fed. Reg. 18661, 18662 (1978) (emphasis added).

In any event, a grant of premarket approval imposes a variety of design, labeling, and manufacturing requirements on the specific device that is approved. By its very nature, PMA approval is a *specific* determination by FDA that a *particular* device is reasonably safe and effective, based on FDA's review of data relating exclusively to that device. See *Buckman*, 531 U.S. at 348 (PMA process "involves a time-consuming inquiry into the risks and efficacy of *each* device") (emphasis added).

As the Second Circuit recognized in this case (Pet. App. 2a, 23a), the vast majority of federal and state courts to have addressed the question – before as well as after *Lohr* – have concluded that the PMA process imposes "specific" federal requirements on approved devices. Most courts have also concluded – correctly – that federal requirements imposed in the PMA process preempt state-law tort claims like those asserted by the petitioner in this case, which seek to impose *different* requirements relating to the design, manufacture, and labeling of a medical device. These conclusions, of course, finds further support in the FDA's interpretation of Section 360k(a), which under *Lohr* is entitled to substantial weight. Pet. App. 37a-38a.

Respondent's brief explains in detail how the premarket approval process works and the legal effect of FDA approval. See also Pet. App. 8a-10a, 25a-27a.[8] It also persuasively demonstrates that, under the *Lohr* framework, petitioner's state-law claims impose "requirements" within the meaning of Section 360k(a) that differ from, or are in addition to, the federal requirements applicable to the Evergreen Balloon Catheter. See also Pet. App. 30a-32a. Rather than repeat respondent's analysis here, we focus below on the substantial evidence from both (1) the legislative history of the MDA, and (2) the FDA's practice of administering exemptions from preemption under 21 U.S.C. § 360k(b), which strongly confirms the Second Circuit's conclusions with respect to preemption.

### A. The Legislative History And FDA's Exemption Practice Confirm That The PMA Process Imposes "Requirements" That Are "Specific"

Petitioner concedes in her brief (at 25-26) that, if the FDA determines that a medical device either "could not be marketed without a federal PMA" or, on the contrary, "did not require [a federal] PMA," that decision would impose a federal "requirement" on the device within the meaning of Section 360k(a) that in turn would "preempt a state requirement that the device undergo" premarket approval before a *state* agency pursuant to *state* law. As petitioner is constrained to admit (at 25), on many occasions the FDA has made clear that the federal requirement of premarket approval triggers express preemption under Section

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[8] Petitioner's contention that PMA approval imposes no requirements *at all* on the device not only misunderstands how the regulatory scheme works but also ignores the many provisions of the MDA that refer to "requirements" imposed by FDA through the PMA process (pursuant to 21 U.S.C. § 360e). See, *e.g.*, 21 U.S.C. § 331(e) (prohibiting, among other things, the "failure to establish or maintain" records "required under" Section 360e(f)); *id.* § 351(f)(1)(A)(I), (B)(I), (c) (in sections relating to adulterated devices, referring to "require[ment]" of having premarket approval); *id.* §§ 360(k)(2), 360c(b)(1)(A), 360c(c)(2)(A), 360c(e)(1)(B), 360e(b), 360e(c)(2), 382(a)(2)(A).

360k(a). See 43 Fed. Reg. 18661, 18664 (1978); accord 45 Fed. Reg. 67321, 67322-23 (1980); 44 Fed. Reg. 19438, 19439 (1979). Petitioner also concedes that, in the absence of an exemption granted by FDA, a state provision such as California's Sherman Food, Drug, and Cosmetic Law would be expressly preempted. Pet. Br. 6-7, 25.

The last conclusion rests on clear evidence in the legislative history of the MDA. Specifically, the House Report accompanying the legislation stated:

> In the absence of effective Federal regulation of medical devices, some States have established their own programs. The most comprehensive State regulation * * * is that of California, which in 1970 adopted the Sherman Food, Drug, and Cosmetic Law. This law requires premarket approval of all new medical devices * * * . * * *
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> In the Committee's view, *requirements imposed under the California statute* serve as an example of requirements that the Secretary should authorize to be continued (provided any application submitted by a State meets the requirements [for exemption] * * * ).

H.R. Rep. No. 94-853, at 45-46 (1976) (emphasis added). Thus, the legislative history strongly confirms Congress's understanding that "requirements imposed under the California statute" – including the requirement of premarket approval of each new medical device – would be preempted by Section 360k(a) unless FDA grants an exemption.

These concessions go far toward establishing that PMA approval imposes federal requirements that are "specific" and trigger preemption under Section 360k(a). Contrary to petitioner's suggestion, the House Report's reference to "*requirements* imposed under the California statute" is not limited to the requirement of *obtaining* premarket approval; rather, it envisions that *all* "requirements imposed under the California statute" would be preempted in the absence of an exemption. In other words, the Committee plainly believed that requirements

imposed pursuant to a state PMA process – including requirements relating to a device's design, manufacture and labeling – would be subject to preemption unless exempted. What would have triggered such preemption? The answer is self-evident: The counterpart design, manufacturing, and labeling requirements imposed through the *federal* PMA process.

Nor is this all. The conference committee that chose the final language of the MDA opted for the preemption clause in the House bill (H.R. 11124, 94th Cong., 2d Sess. (1976)) instead of the narrower version in the Senate bill (S. 510, 94th Cong., 1st Sess. (1975)). See H.R. Conf. Rep. 94-1090, at 40 (1976). The Senate bill provided:

> Sec. 903. (a) Whenever a performance standard pursuant to section 513 or *scientific review pursuant to section 514 under this Act is in effect*, no State or political subdivision of a State shall have any authority either to establish or to continue in effect any provision of a standard or regulation which prescribes *any requirements* as to the *performance, composition, contents, design, finish, construction, packaging, or labeling* of such product which are designed to deal with the same device unless such requirements are identical to the requirements of *the Federal requirements*.

S. Rep. No. 94-33, at 72-73 (1975) (emphasis added). The reference to "Section 514" was to the process for premarket scientific review in the Senate bill. Thus, the Senate bill plainly envisioned that federal premarket approval would impose requirements that would have preemptive effect. There is no reason to think that Congress, in choosing the *broader* language of the House bill, intended a *narrower* form of preemption that would not be triggered by federal PMA requirements.

The FDA's exemption practice provides further support for the conclusion that requirements imposed through the PMA process trigger express preemption. Illustrative is a post-*Lohr* advisory opinion issued by the FDA on December 18, 1996, in which the agency opined that certain requirements imposed

through the PMA process on an over-the-counter HIV-test kit (known as the "Home Access" test) preempted divergent requirements imposed under state law. See Addendum ("Add.") 1a-5a (reproducing FDA's advisory opinion). Specifically, the FDA explained (Add. 3a):

> The testing protocol proposed by Home Access and approved by FDA provides for the device to be mailed by the client to the laboratory in a preaddressed envelope contained in the kit. Both the New York and California provisions * * * would require referral to the laboratory by a physician or other licensed health professional rather than by the client himself or herself. These requirements, as applied to the Home Access test system are different from the requirements in FDA's approval order. Consequently, these provisions, as applied to the Home Access test system, are preempted under Section [360k(a)] of the act.

The FDA's exemption practice also refutes any suggestion that "specificity" on the federal side is limited to requirements that apply only to a single medical device. During the period the agency regulated cigarettes as a medical device, for example, several of the exemptions considered by FDA involved federal regulations relating to both cigarettes and smokeless tobacco. See 21 C.F.R. § 897.1 *et seq.* (1998); 62 Fed. Reg. 7390 (1997); 62 Fed. Reg. 63271 (1997).[9] And shortly after the MDA was enacted, the FDA considered – and denied – a request by California seeking an exemption from preemption from the federal good manufacturing practices (GMP) regulations, which

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[9] In its *amicus* brief in *Buckman*, the United States gave various examples of federal requirements that qualify as applicable "to a specific device or set of devices" and thus trigger express preemption. 98-1768 U.S. Br., 2000 WL 1364441, at *12. Those examples include federal requirements that apply to all medical devices that contain natural rubber (21 C.F.R. § 801.437) – in all, *43 different categories* comprising *17,600 different models* of medical devices, including catheters, latex gloves, tracheal tubes, condoms, enema kits, and ophthalmic eyeshields. 63 Fed. Reg. 50660, 50673-50676 (1998).

California had adopted as its own, insofar as California wished to interpret them in a way different from FDA. See 45 Fed. Reg. 67321, 67322 (1980) ("if California interprets or applies the GMP regulations in such a way as to make them different from or in addition to the Federal regulations, then the California requirements *will be preempted* to that extent") (emphasis added). That action, of course, presupposes that the federal GMPs, despite their general applicability to virtually *all* medical devices, have preemptive effect under Section 360k(a). To be sure, this Court in *Lohr* reached the opposite conclusion about the preemptive effect of the federal GMP requirements (evidently without being aware of this evidence from the FDA's exemption practice), but that does not change FDA's prior exemption practice.[10] In sum, the MDA's legislative history and FDA's exemption practice remove any doubt about whether the PMA process imposes preemptive federal requirements.[11]

### B. The Legislative History And FDA's Exemption Practice Confirm That Petitioner's Claims Would Impose State-Law "Requirements" That Are "Specific" On The Evergreen Balloon Catheter

In *Lohr*, a majority of this Court concluded that Section 360k(a)'s reference to state "requirements" includes requirements imposed by the common law, even though common law

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[10] Consistent with FDA's early exemption practice, the United States *expressly conceded* in its *amicus* brief in *Lohr* that the requirements imposed in the GMP regulations give rise to preemption of state requirements. See Nos. 95-754, 95-886 U.S. Br., 1996 WL 118035, at *24 n.19 ("We do not dispute that the GMPs impose 'requirement[s]' within the meaning of Section [360k(a)].").

[11] Petitioner's contention that the PMA does not impose design and other requirements because design choices may originate in the manufacturer rather than the agency conflates the genesis of an obligation with whether the obligation is binding. Private parties may petition FDA to make rules and regulations. See 21 C.F.R. §§ 10.25(a), 10.30, 10.40(a)(2). Requirements eventually imposed by the agency are in no way optional just because they originated in the proposal of a private party.

duties are not limited to medical devices but apply to a wide array of products and persons. The reason is straightforward: such duties can be and are routinely applied every day to particular medical devices in product liability litigation. The end result of such specific application of tort law to a particular device is the imposition of device-specific requirements within the meaning of the FDA's regulation. As the Solicitor General explained on behalf of the FDA during the Clinton Administration: "Section 360k(a) does preempt a specific duty of care that is made applicable to a device through application in litigation of a State's common law of torts, if that requirement is different from, or in addition to, a specific requirement imposed by FDA." No. 98-1768 U.S. Br., *Buckman* v. *Plaintiffs' Legal Committee*, 12-13 n.1.

This conclusion is confirmed by evidence from the legislative history of the MDA as well as the FDA's exemption practice. As noted above, petitioner acknowledges that Congress had in mind California's Sherman Food, Drug, and Cosmetic Law when it enacted the exemption provision, 21 U.S.C. § 360k(b). Thus, Congress clearly was of the view that, in the absence of an exemption granted by FDA, this California statute would be preempted by Section 360k(a). The California statute's "requirements," in other words, would fall within Section 360k(a). Significantly, however, California's Sherman Law *did not apply only to medical devices*. Instead, as its full name suggests, the Sherman Act also applied to drugs and cosmetics.[12]

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[12] See, *e.g.*, 21 CAL. HEALTH & SAFETY CODE § 26614 (1984) (providing that "any drug or device" is adulterated if it bears or contains for the purpose of coloring only a coloring additive which is unsafe within the meaning of the Sherman Act); *id.* § 26615 (another provision relating to adulteration of drugs and devices); *id.* § 26618 ("Any drug or device is adulterated if any substance has been mixed or packed with it so as to reduce its quality or strength or if any substance has been substituted, wholly or in part, for the drug or device"); *id.* §§ 26631, 26640, 26641 (provisions regulating misbranding of both drugs and devices). The FDA has concluded that all of the foregoing provisions are preempted by Section 360k(a) but only "to the extent that they apply to devices." 21

Thus, the legislative history confirms that a state requirement could be preempted under Section 360k(a) even if it was in theory applicable to products other than medical devices.

FDA's exemption practice further refutes petitioner's submission that a state requirement can never be "device-specific" if it is traceable to a law that applies to products other than medical devices. The FDA has acted on at least a dozen requests for preemption exemptions for state provisions that apply not only to medical devices but also to other products. See 21 C.F.R. § 808.55(b)(1), (2) (denying exemptions for nine separate provisions of California statute "to the extent that they apply to devices"). See also 21 C.F.R. § 808.51 (1999) (exempting Alabama statute "[t]o the extent that" it applies to medical devices); *id.* § 808.52 (same for Alaska statute); *id.* § 808.94 (exempting Utah statute "[t]o the extent" it applies to medical devices). And FDA has made clear that even "general [state] requirements not applicable to specific devices" are covered by Section 360k(a) once they are "applied to a specific device in such a way as to establish requirements." 45 Fed. Reg. 67321, 67322 (1980). That principle is dispositive here.

FDA's exemption practice since *Lohr* has continued to reflect this understanding. Thus, in evaluating exemption requests for state and local requirements relating to cigarettes and smokeless tobacco, the agency considered several state statutes even though they applied to products other than what the agency then regarded as medical devices. See 62 Fed. Reg. 7390, 7392 (1997); 62 Fed. Reg. 63271, 63272 (1997). For example, the agency considered whether to exempt an Alabama statute that applied to "cigarettes, cigarette tobacco or *cigarette paper*, or *any substitute for either of them*." 62 Fed. Reg. at 7391 (quoting ALABAMA CODE § 13A-12-3 (2007) (emphasis added)). And in the FDA's advisory letter relating to the Home Access HIV-test kit, the agency made clear that "[w]hile state licensing and certification requirements generally are not

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C.F.R. § 808.55(b)(1). See also note 13, *infra*.

preempted under Section [360k(a)] (See 21 C.F.R. 808.1(d)(3)), they are preempted when they impose requirements on a particular device that are different from or in addition to specific counterpart requirements imposed" by federal law. Add. 4a.

## III. The Court Should Reconsider The "Specificity" Gloss On 21 U.S.C. § 360k(a)

Under the framework established in *Lohr*, petitioner's claims are preempted by Section 360k(a). But if the Court disagrees with that submission, then it should take this opportunity to revisit and reconsider its equivocal conclusion in *Lohr* that express preemption under Section 360k(a) applies only to "specific" requirements. See note 3, *supra*. With all due respect, the four dissenting Justices in *Lohr* were correct when they observed that "[t]he statute makes no mention of a requirement of specificity, and there is no sound basis for determining that such a restriction on 'any requirement' exists." 518 U.S. at 512 (opinion of O'Connor, J.).

*Stare decisis* "is a principle of policy rather than an inexorable command." *Hohn* v. *United States*, 524 U.S. 236, 251 (1998) (citation and quotation marks omitted). Although the doctrine has more force in statutory cases, this Court has "never applied *stare decisis* mechanically to prohibit overruling * * * earlier decisions determining the meaning of statutes." *Monell* v. *New York City Dep't of Soc. Servs.*, 436 U.S. 658, 695 (1978). In this case, there is a "special justification" (*Arizona* v. *Rumsey*, 467 U.S. 203, 212 (1984)) for revisiting this aspect of *Lohr*: it rests on a clear misunderstanding of the FDA's regulatory notices and exemption practice.

A. The FDA's interpretation of Section 360k(a) was first set forth in the two notices proposing and then promulgating 21 C.F.R. § 808.1(d), which concerns procedures for obtaining exemptions from preemption under 21 U.S.C. § 360k(b). See 42 Fed. Reg. 30383 (1977) (proposing rule); 43 Fed. Reg. 18661 (1978) (final rule). It was in these notices that the agency first put forward its "specificity" gloss on the preemption provision.

A careful examination of these regulatory notices, however, reveals that the specificity concept was intended to be a limitation only on *state* (not on *federal*) requirements under Section 360k(a). As both the 1977 and 1978 notices make clear, the FDA regarded as an open question whether, under the language of Section 360k(a), a federal requirement *must be in existence* before counterpart state requirements are preempted. Thus, in the 1977 preamble to the proposed rule, the agency stated that

> [c]onsistent with his understanding of the intent of Congress, the Commissioner has *narrowly construed* the preemption provision so that section [360k(a)] * * * preempts State and local requirements only when a *particular Federal requirement becomes applicable to a particular device* by operation of the act. This avoids disruption of vital State and local programs * * * and reduces the possibility of a regulatory hiatus that could result if State or local requirements were considered preempted *prior to the time FDA implemented Federal requirements*. The potential for such a regulatory void is real since it will require several years for FDA to implement fully its device regulatory programs.

42 Fed. Reg. at 30383 (emphasis added); accord *id.* at 30384 (same).

In the 1978 notice, FDA pointed out that "[m]any comments" filed in response to the proposed rule had taken issue with the Commissioner's position that a federal requirement must be in place before state requirements are preempted. 43 Fed. Reg. at 18662. "The comments generally argued that *all* State and local medical device requirements were preempted as of May 28, 1976, the date of enactment of the Medical Device Amendments of 1976." *Ibid.* (emphasis added). It was in rejecting this precise argument that the FDA stated, echoing language in its final regulation, that "the scope of preemption is limited to instances where there are specific FDA requirements applicable to a particular device or class of devices." *Ibid.* See 21 C.F.R. § 808.1(d) ("State or local requirements are preempted only when the Food and Drug Administration has established

specific counterpart regulations or there are other specific requirements applicable to a particular device * * *.").

Read in the context of the underlying notices, then, 21 C.F.R. § 808.1(d)'s reference to "specific FDA requirements applicable to a particular device or class of devices" was not intended as a limitation on the *type* of federal requirements that would trigger express preemption. By indicating that there must be "specific FDA requirements" in place before preemption occurs, the agency was saying nothing more than that some federal requirement must actually be in place (not merely be capable of being put in place) before counterpart state requirements are preempted. Other regulatory notices also support this interpretation. See, *e.g.*, 45 Fed. Reg. 67321, 67321-22 (1980); 42 Fed. Reg. 9186, 9186 (1977).

B. In adopting the "specificity" requirement as a gloss on Section 360k(a), the *Lohr* majority reasoned that "the FDA has never granted, nor, to the best of our knowledge, even been asked to consider granting, an exemption for a state law of general applicability." 518 U.S. at 499-500. This is untrue. In fact, as explained above, the FDA has *repeatedly* treated state requirements "of general applicability" (21 C.F.R. § 808.1(d)(1)) – in the sense that they have a "purpose" that "relates * * * to other products in addition to devices" (*ibid.*) – as eligible for exemption from express preemption. Perhaps the best example is California's Sherman Food, Drug and Cosmetic Law, which contains numerous provisions that pertain to drugs as well as to medical devices. See note 21, *supra*; 44 Fed. Reg. 19440 (1979); 21 C.F.R. § 808.55(b)(1).[13] Moreover, the FDA also considered

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[13] For example, the FDA has determined that Section 360k(a) preempts a California provision that makes it unlawful "for any person to *advertise* any *drug or device represented to have any effect* in any of the following conditions, disorders, or diseases: * * * (m) [d]iseases or disorders of the ear or auditory apparatus, including hearing loss and deafness." 21 CAL. HEALTH & SAFETY CODE § 26463(m) (1984) (emphasis added). According to the FDA, this provision is preempted "to the extent that it applies to hearing aids." 21 C.F.R. § 808.55(b)(2); 45 Fed. Reg. at 67322.

California's request for an exemption of its GMP requirements, which applied to all kinds of devices. See pages 22-23, *supra*.

Nor is this all. As explained above (at 14), the Solicitor General acknowledged in *Lohr* that the text of Section 360k(a) – and in particular Congress's use of the phrase "with respect to" – in fact "suggests that" a state requirement covered by the preemption clause "may be one of general applicability." Nos. 95-754, 95-886 U.S. Br. 18. The FDA's "specificity" gloss, in other words, is inconsistent with the text of Section 360k(a). And yet FDA's reasons for engrafting the "specificity" limitation on Section 360k(a) in the first place were (1) the supposed absence in the MDA's legislative history of any reference to generally applicable state requirements as imposing undue burdens on interstate commerce (which overlooks or ignores Congress's mention of California's Sherman Law); and (2) a stilted interpretation of the "with respect to" phrase that the Solicitor General in his *Lohr* brief described as "strained as a grammatical matter" and repudiated. See 42 Fed. Reg. at 30384; 43 Fed. Reg. at 18663. Both of the original rationales for the "specificity" gloss on state "requirements" are thus mistaken (and one has been repudiated).

C. A final reason why the Court should abandon the "specificity" gloss is that it makes no sense. Why would Congress have meant to preempt "different" or "additional" state requirements imposed by laws that apply exclusively to medical devices, but to preserve the *very same requirements* if imposed by laws (like California's Sherman Law) that apply to other products as well? In either case, the impact on uniformity and on the federal scheme is exactly the same. Nor is there any good reason to think Congress would have wanted to allow States and local governments to evade preemption through the simple expedient of skillful drafting.

Not surprisingly, this Court has repeatedly rejected invitations to read similar limitations into other express preemption provisions. Illustrative is *Morales* v. *Trans World Airlines, Inc.*, 504 U.S. 374 (1992), which involved a provision of the Airline

Deregulation Act of 1978 ("ADA") that "pre-empts the States from 'enact[ing] or enforc[ing] any law, rule, regulation, standard or other provision * * * relating to rates, routes, or services of any air carrier.'" *Id.* at 383 (quoting 49 U.S.C. App. § 1305(a)(1)). The Court categorically rejected the argument that "only state laws specifically addressed to the airline industry are pre-empted, whereas the ADA imposes no constraints on laws of general applicability." *Id.* at 386. Such an interpretation, this Court noted, would create "an utterly irrational loophole." *Ibid.* (emphasis added).[14] That criticism applies with equal force here. Accordingly, the Court should take this opportunity to eliminate this "utterly irrational loophole" from the law of express preemption under the MDA.[15]

## CONCLUSION

The judgment of the court of appeals should be affirmed.

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[14]Accord *Pilot Life Ins. Co.* v. *Dedeaux*, 481 U.S. 41, 47-48 (1987) (ERISA preemption is not limited to state measures targeting ERISA plans but also includes more general common law tort and contract causes of action); *San Diego Bldg. Trades Council* v. *Garmon*, 359 U.S. 236, 244 & n.3 (1959) ("Nor has it mattered [in cases involving NLRA preemption] whether the States have acted through laws of broad general application rather than laws specifically directed towards the governance of industrial relations.").

[15] Notably, the United States in *Lohr* did *not* urge this Court to adopt, or even to defer to, the "specificity" concept expressed in 21 C.F.R. § 808.1(d).

Respectfully submitted.

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OCTOBER 2007

# ADDENDUM

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service

Rockville MD 20857

DEC 18, 1996

[docket file-stamp omitted]

Robert P. Brady, Esq.
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Dear Mr. Brady:

This is in response to your request for an advisory opinion concerning the preemptive effect of Section 521 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k) ("the act") on certain New York and California statutes as applied to the HIV-1 Home Test Kits of Home Access Health Corp.

Section 521(a) of the act provides that no State or local government may establish or continue in effect any requirement with respect to a medical device that is different from or in addition to any requirement under the act applicable to the device, which relates to the safety or ineffectiveness of the device or any other requirement applicable to the device under the act. State or local requirements are preempted only when FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act (21 C.F.R. 808.1(d)).

The Home Access Approval:

On July 22, 1996, FDA approved the Home Access™ HIV-1 Test System ("the Home Access test"). The approval order states that the device is indicated for self-use by people who wish to obtain anonymous testing. The approved collection kit

contains the materials necessary to collect blood specimens in the privacy of the home and to ship the specimens to a qualified dedicated testing laboratory. The client follows instructions in the collection kit to collet a blood specimen and places it in a pre-addressed, prepaid return envelope. The specimens are shipped to a dedicated laboratory meeting Clinical Laboratory Improvement Act (CLIA) requirements and the approval order, Mid-American Technologies, Inc., Olathe, Kansas is the only laboratory qualified to conduct the testing of specimens of the Home Access™ HIV-1 Test System. Testing by any other laboratory would require approval of a premarket approval (PMA) supplement by FDA.

Over-the-Counter (OTC) versus Prescription Use:

You have asked for an advisory opinion concerning the preemptive effect of Section 521 of the act on California and New York requirements which, if applied to the Home Access test, would require that laboratories accept specimens only upon the order of a physician or other licensed health professional.

Section 1288 of the California Business and Professions Code provides that: [a]ny person conducting or operating a clinical laboratory may accept assignments for tests only from and make reports only to persons licensed under the provisions of law relating to the healing arts or their representatives.

The California Business and Professions Code Section 1246.5 provides an exception to this requirement for certain listed tests (not including the Home Access test) and further provides that a test may be added to the list, after it has been approved by FDA for OTC use. It does not appear that California has at this time added the Home Access test to this list.

The New York Comp. Codes R. & Regs tit. 10, 58-1.7(b) provides that: clinical laborator[ies] shall examine specimens only at the request of licenced physicians or other persons authorized by law to use the findings of laboratory examinations

in their practice or the performance of their official duties. New York does not provide for any exceptions to this requirement.

As noted above, in approving the Home Access test, FDA made a determination that the test may be distributed for self-use by persons who wish to obtain anonymous HIV testing, in other words for "over-the-counter" (OTC) use. The testing protocol proposed by Home Access and approved by FDA provides for the device to be mailed by the client to the laboratory in a preaddressed envelope contained in the kit. Both the New York and the California provisions cited above would require referral to the laboratory by a physician or other licensed health professional rather than by the client himself or herself. These requirements, as applied to the Home Access test system are different from the requirements in FDA's approval order. Consequently, these provisions, as applied to the Home Access test system, are preempted under Section 521 of the act.

State Laboratory Permit Requirements:

You also ask for an advisory opinion on whether the following provisions concerning laboratories performing HIV testing are preempted as applied to the Home Access test:

1. N.Y. Comp. Codes R. & Regs. tit. 10, at 58-1.1(a) This provision requires that clinical laboratories obtain a permit from the New York Commissioner of Health and that a permit may not be issued to a laboratory unless it has been inspected by the Department of Health. It further provides that a clinical laboratory shall perform only those tests that are within the categories stated on its permit.

2. Section 1039.2 of the California Code of Regulations. This section requires that laboratory personnel be certified for the type and complexity of testing performed.

3. Section 1230(e) of the California Code of Regulations. This section provides that approved laboratories shall perform confirmatory testing on all specimens with a positive HIV

screening result using FDA approved Western blot kids or the immunofluorescence method developed and used by the California Department of Health Services.

Both of the statutes contain provisions making these requirements applicable to out of state laboratories accepting specimens from these states.

While state licensing and certification requirements generally are not preempted under Section 521(a) (See 21 C.F.R. 808.1(d)(3)), they are preempted when they impose requirements on a particular device that are different from or in addition to specific counterpart requirements imposed on that particular device under the act. The approval order for the Home Access test specifically requires that testing be conducted by the Mid-American Technologies, Inc. (MAT) laboratory. Before approving the MAT laboratory, FDA performed an inspection of the laboratory to determine whether it was in compliance with all applicable regulations governing matters such as process and software validation, buildings, environment, and personnel. The inspectors witnessed a validation run of assays of the Home Access test kit. The New York provisions in 58-1.1(a) above and Section 1039.2 of the California Code of Regulations, if applied to MAT testing under the Home Access test system would impose licensing and certification requirements with respect to the Home Access test that are in addition to, and perhaps different from, specific requirements under the approval process and, consequently, are preempted under Section 521 of the act. These provisions are preempted only to the extent that they are applied to MAT with respect to the Home Access test kit.

Similarly, the requirements for confirmatory testing set out in Section 1230(e) of the California Business and Professions Code are also preempted, as applied to the Home Access test kit. The FDA approval requires confirmatory testing only with a test approved by FDA. The California requirement for confirmatory testing allow for confirmatory testing with an immunofluorescence method not approved by FDA and, therefore, is different from the FDA requirements.

If you have any questions about this advisory opinion, you may contact Joseph M. Sheehan of our Center for Devices and Radiological Health at (301) 827-2974.

Sincerely yours,

/s/

William B. Schultz
Deputy Commissioner for Policy

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(9)

No. 06-179

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IN THE

# Supreme Court of the United States

CHARLES R. RIEGEL AND DONNA S. RIEGEL, *Petitioners*

*v.*

MEDTRONIC, INC., *Respondent*

*ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT*

## BRIEF OF CONSUMERS UNION OF UNITED STATES, INC., AS *AMICUS CURIAE* IN SUPPORT OF PETITIONERS

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## QUESTION PRESENTED

Whether the express preemption provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), preempts state-law claims seeking damages for injuries caused by medical devices that received premarket approval from the Food and Drug Administration.

## TABLE OF CONTENTS


Page

Interest of *Amicus Curiae* ..... 1

Summary of Argument..... 2

Argument:

I. The Food, Drug, And Cosmetic Act Sets Minimum Standards, Designed To Continually Improve The Safety Of Regulated Products, And Thus The Statute Fits Comfortably With State-Based Common Law Remedies ..... 4

II. This Court's Recent Rulings On Preemption Must Be Understood With Reference To The Specific Regulatory Settings In Which They Arose..... 11

III. The Medical Device Amendments Do Not Preempt The Petitioners' Tort Claims..... 16

## TABLE OF AUTHORITIES

Cases: Page

*62 Cases, More or Less, Each Containing Six Jars of Jam v. U.S.*, 340 U.S. 593 (1951) ..... 5
*Abbott Labs. v. Lapp*, 78 F.2d 170 (7th Cir. 1935) ..... 7
*Bates v. Dow Agroscience LLC*, 544 U.S. 431 (2005) . .14-16, 17
*Berry v. Am. Cyanamid Co.*, 341 F.2d 14 (6th Cir. 1965) .. 8
*Bine v. Sterling Drug, Inc.*, 422 S.W.2d 623 (Mo. 1968) .... 8
*Cinocca v. Baxter Lab., Inc.*, 400 F. Supp. 527 (E.D. Okla. 1975) ..... 9
*Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) ... 12, 15
*Coca Cola Bottling Works v. Selvidge*, 4 Tenn. App. 558 (Tenn. App. 1927) ..... 7
*Crocker v. Winthrop Labs., Div. of Sterling Drug, Inc.*, 514 S.W.2d 429 (Tx. 1974) ..... 8
*Croft v. York*, 244 So.2d 161 (Fla. App. 1971) ..... 8
*Davis v. Wyeth Labs., Inc.*, 399 F.2d 121 (9th Cir. 1968) ... 8
*Dreiling v. Gen. Elec. Co.*, 511 F.2d 768 (5th Cir. 1975) .... 9
*E.R. Squibb & Sons, Inc. v. Jordan*, 254 So.2d 17 (Fla. App. 1971) ..... 9
*Friedman v. Medtronic, Inc.*, 345 N.Y.S.2d 637 (NY App. Div. 1973) ..... 9
*Fritz v. Parke Davis & Co.*, 277 Minn. 210 (Minn. 1967) ... 8
*Geier v. Am. Honda Motor Co.*, 529 U.S. 861 (2000) ..... 4
*Grinnell v. Charles Pfizer & Co.*, 79 Cal. Rptr. 369 (Cal. Ct. App. 1969) ..... 8
*Henry v. Richardson-Merrell, Inc.*, 508 F.2d 28 (3d Cir. 1975) . ..... 8
*Hoffman v. Sterling Drug, Inc.*, 374 F. Supp. 850 (M.D. Pa. 1974) ..... 8
*Hornung v. Richardson-Merrill, Inc.*, 317 F. Supp. 183 (D. Mont. 1970) ..... 8
*Hruska v. Parke, Davis & Co.*, 6 F.2d 536 (8th Cir. 1925) .. 7

Cases—Continued: Page

*In re A. H. Robbins Co., Inc. "Dalkon Shield" IUD Prod.s Liab. Litig.*, 406 F. Supp. 540 (J.P.M.L. 1975) . . . . . 10
*Kershaw v. Sterling Drug, Inc.*, 415 F.2d 1009 (5th Cir. 1969) . . . . . 8
*Kordel v. United States*, 335 U.S. 345 (1948) . . . . . 7
*Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143 (Mo. 1967) . . . 8
*Love v. Wolf*, 58 Cal. Rptr. 42 (Cal. Ct. App. 1967) . . . . . 8
*Machlitt v. Myers*, 23 Ohio App. 160 (Ohio App. 1926) . . . 7
*Mazetti v. Armour & Co.*, 75 Wash. 622 (Wash. 1913) . . . . . 7
*McEwen v. Ortho Pharm. Corp.*, 270 Or. 375 (Or. 1974) . . . . 8
*Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996). 2, 4, 10, 13-15, 17
*Moehlenbrock v. Parke, Davis & Co.*, 141 Minn. 154 (Minn. 1918) . . . . . 7
*Oresman v. G. D. Searle & Co.*, 388 F. Supp. 1175 (D. R.I. 1975) . . . . . 8
*Orthopedic Equip. Co. v. Eutsler*, 276 F.2d 455 (4th Cir. 1960) . . . . . 9
*Parke-Davis & Co. v. Stromsodt*, 411 F.2d 1390 (8th Cir. 1969) . . . . . 8
*Redfield v. Mead, Johnson & Co.*, 266 Or. 273 (Or. 1973) . . . 8
*Reyes v. Wyeth Labs.*, 498 F.2d 1264 (5th Cir. 1974) . . . . . 8
*Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 (1947) . . . . . 11
*Riegel v. Medtronic, Inc.*, 451 F.3d 104 (2d Cir. 2006) . . . . 16
*Ritchie v. Sheffield Farms Co.*, 222 N.Y.S. 724 (N.Y. Mun. Ct. 1927) . . . . . 7
*Salmon v. Parke, Davis & Co.*, 520 F.2d 1359 (4th Cir. 1975) . . . . . 8
*Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919 (8th Cir. 1970) . . . . . 8
*Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238 (1984) . . . . . 11
*Singer v. Sterling Drug, Inc.*, 461 F.2d 288 (7th Cir. 1972) . . 8
*Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002) . . . . . 13
*Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966) . 8

Cases—Continued: Page

*Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978 (8th Cir. 1969) . 8
*Stevens v. Parke, Davis & Co.*, 507 P.2d 653 (Cal. 1973) . . . 8
*Tinnerholm v. Parke, Davis & Co.*, 411 F.2d 48 (2d Cir. 1969) . . . . . 7
*Toole v. Richardson-Merrell Inc.*, 60 Cal.Rptr. 398 (Cal. Ct. App. 1967) . . . . . 8
*United States v. Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784 (1969) . . . . . 6, 7
*United States v. Dotterweich*, 320 U.S. 277 (1943) . . . . . 5, 10
*United States v. Park*, 421 U.S. 658 (1975) . . . . . 10
*Vergott v. Deseret Pharm. Co.*, 463 F.2d 12 (5th Cir. 1972) . 9
*Wechsler v. Hoffman-La Roche, Inc.*, 99 N.Y.S.2d 588 (N.Y. Sup. 1950) . . . . . 8
*Wennerholm v. Stanford Univ. Sch. of Med.*, 128 P.2d 522, (Cal. 1942) . . . . . 7-8
*Whitley v. Cubberly*, 210 S.E.2d 289, (N.C. Ct. App. 1974) . 8
*Williams v. Vick Chemical Co.*, 279 F. Supp. 833 (S.D. Iowa 1967) . . . . . 8

Statutes:

Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 . . . . . 5
Federal Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768 . . . . . 4
Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, 52 Stat. 1040 . . . . . 5, 6
(*codified as amended at* 21 U.S.C. §§ 301 *et seq.* (2006)):
21 U.S.C. § 331 . . . . . 5
21 U.S.C. § 351 . . . . . 5
21 U.S.C. § 360e(d)(2)(A), (B) . . . . . 17
21 U.S.C. § 360h(d) . . . . . 17
21 U.S.C. § 360h(e) . . . . . 6
21 U.S.C. § 360h(e)(1)(B) . . . . . 6

Statutes—Continued: Page

21 U.S.C. § 360k(a) ..... 16
21 U.S.C. § 360*l* ..... 6
Medical Device Amendments of 1976, Pub. L. 94-295, 90 Stat. 539 ..... 5

Miscellaneous: Page

S. Rep. 94-33 (1975), 94 Cong. 2d Sess., *as reprinted in* 1976 U.S.C.C.A.N. 1070 ..... 9
David Owen, *Federal Preemption of Products Liability Claims*, 55 S.C. L. REV. 411, 423 (2003) ..... 12
David C. Vladeck, *Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95, 106 (2005) ..... 12

## BRIEF OF AMICUS CURIAE CONSUMERS UNION OF UNITED STATES, INC., IN SUPPORT OF PETITIONERS

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### STATEMENT OF INTEREST OF *AMICUS CURIAE*[1]

Consumers Union of United States, Inc., the publisher of *Consumer Reports*, is a non-profit membership organization chartered in 1936 to provide consumers with information, education, and counsel about goods, services, health, and personal finance. Consumers Union's publications have a combined paid circulation of approximately 8 million. These publications regularly carry articles reporting on Consumer Union's own product testing; health, product safety, and marketplace economics; and legislative, judicial, and regulatory actions that affect consumer welfare. Consumers Union's income is solely derived from the sale of *Consumer Reports*, its other publications and services, and from noncommercial contributions, grants, and fees. Consumers Union's publications and services carry no outside advertising and receive no commercial support.

Consumers Union's mission is to work for a fair, just, and safe marketplace for all consumers and to empower consumers to protect themselves. In line with that mission

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[1] The parties have lodged letters with the Court consenting generally to the filing of briefs *amicus curiae*, and accordingly, the parties have consented to the filing of this brief. See Sup. Ct. R. 37.3(a). No counsel for a party to this case authored this brief in whole or in part, and no person or entity other than *Amicus Curiae* Consumers Union, its members, or its counsel, made a monetary contribution to the preparation or submission of the brief. See Sup. Ct. R. 37.6.

and our assessment of priorities, Consumers Union has actively worked for a fair and just marketplace for consumers in critical areas implicated by this case, including health care and prescription drugs. From its beginnings, on through the present time, Consumers Union has filed actions in both state and federal courts to protect consumers, and has participated in a variety of proceedings before both state and federal regulatory agencies. Consumers Union played an active role in securing the passage of the Food, Drug, and Cosmetic Act of 1938 and the 1958 amendments to the Act. Consumers Union also filed an amicus brief in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), a decision of central importance to this case.

## SUMMARY OF ARGUMENT

In 1996, Charles Riegel had an angioplasty performed on his right coronary artery. During the procedure, Mr. Riegel's surgeon used respondent Medtronic's Evergreen Balloon Catheter. The catheter burst inside Mr. Riegel's artery, causing Mr. Riegel severe and permanent injuries and disabilities. In addition, his wife, Donna Riegel, suffered a loss of companionship with her husband. The Riegels sued Medtronic, alleging common-law claims for, among other things, defective design and inadequate warning.

Nothing in the Food, Drug, and Cosmetic Act required Medtronic to manufacture and distribute a negligently and defectively designed catheter with negligently chosen labeling. The law aims higher than that, toward a state of affairs in which the manufacturers of medical devices and other products covered by the statute are under a continuing obligation to ensure the safety of their products.

Nevertheless, the court below held that the Riegels' state-law claims were preempted by the Medical Device

Amendments of 1976 to the Food, Drug, and Cosmetic Act. The court's sweeping ruling reflects a misunderstanding of the federal statute at issue, a misapplication of this Court's precedents, and a misreading of the specific provision on preemption in play in this case.

**1.** The Food, Drug, and Cosmetic Act aims to protect the health of American consumers by regulating foods, drugs, cosmetics, medical devices, and other products and technologies associated with health and health care. A careful reading of the statute reveals a regulatory system designed to set minimum standards for covered products and to press regulated entities to continually improve the safety of their goods. The Act, in its overall substance and structure, fits comfortably with state-created common law aimed at protecting the health and safety of American consumers and providing recompense to those injured through no fault of their own.

**2.** This Court's precedents on preemption dictate a close analysis of both the purportedly preemptive federal law and the purportedly preempted state rule. Indeed, the Court's recent cases in this area can only be understood by reference to the very specific legal settings from which they arose. These cases reflect the Court's traditional wariness about preempting state laws protecting health and safety. The care with which the Court in recent cases has examined the specific legal setting at issue reaffirms the Court's longstanding acknowledgment that federal preemption of state health and safety laws is strong medicine, not to be taken lightly.

**3.** This case falls within the line of decisions from this Court narrowly construing the scope of statutory preemption. The premarket approval of Medtronic's catheter by the Food and Drug Administration is not a "requirement"

absolving Medtronic of liability for negligence and other torts; preserving the Riegels' tort claims creates no tension with that approval; the standard for approving medical devices implies the existence of post-market remedies; and the history of tort litigation preceding the Medical Device Amendments of 1976 strongly reinforces the conclusion that these amendments do not preempt the claims at issue here.

## ARGUMENT

### I. The Food, Drug, And Cosmetic Act Sets Minimum Standards, Designed To Continually Improve The Safety Of Regulated Products, And Thus The Statute Fits Comfortably With State-Based Common Law Remedies.

In determining whether a federal statute preempts state law, this Court has repeatedly stressed the importance of close examination of the statute's text, history, and structure. See, *e.g.*, *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485-486 (1996). In undertaking this inquiry, the Court has found it necessary to look beyond specific provisions on preemption to the broader context of a regulatory scheme in order to responsibly decide the question of preemption. See, *e.g.*, *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 869-874 (2000). Thus, before studying the preemption provision at issue here, a careful look at the broader context of the Federal Food, Drug, and Cosmetic Act is in order.

The Food, Drug, and Cosmetic Act is perhaps the premier consumer protection law in this country. Its basic structure dates back over 100 years, to the Federal Food and Drugs Act of 1906, ch. 3915, 34 Stat. 768. That early enactment created a regulatory framework which, despite many intervening amendments, still exists (albeit in modified form) today. The Medical Device Amendments of 1976 comprise but one piece of this venerable and complex statute. For this reason as well, the preemption provision of

these amendments cannot be well understood without an appreciation of the larger statutory framework of which it is a part.

Careful review of the statutory framework as it has evolved over time reveals several important features relevant to this case. First, in adding new requirements to the statute, Congress tended to keep in place the basic framework that had preceded them. The statute as originally developed in 1906 regulated foods and drugs. *United States v. Dotterweich*, 320 U.S. 277, 280 (1943). It protected American consumers against the twin evils of dangerousness and deception through prohibitions on "adulteration" and "misbranding." *62 Cases, More or Less, Each Containing Six Jars of Jam v. United States*, 340 U.S. 593, 596 (1951). When Congress stiffened the requirements for drugs – in 1938, by providing for premarket review to assess safety, Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No. 75-717, § 505, 52 Stat. 1040, 1052, and in 1962, by requiring review to assess effectiveness, Drug Amendments of 1962, Pub. L. No. 87-781, § 102(a), 76 Stat. 780, 781 – it left the prohibitions against adulteration and misbranding in place. 21 U.S.C. §§ 331, 351. Congress did the same when it added premarket approval requirements for medical devices to the statute in 1976. Medical Device Amendments of 1976, Pub. L. No. 94-295, § 515(a), 90 Stat. 539, 552-553; 21 U.S.C. §§ 331, 351. Thus, drugs and devices approved by the FDA are still subject to the law's prohibitions on adulteration and misbranding. The Food, Drug, and Cosmetic Act is, in short, a palimpsest, a tablet on which the newest layers of writing do not erase earlier ones. The Court should be exceptionally chary of an interpretation of the statute that would use a new regulatory layer (the Medical Device Amendments) to sweep away an old one (state-based remedies of the common law).

Second, while Congress often responded to emerging problems with broader or more stringent premarket review of consumer products, it also retained and strengthened statutory provisions creating a continuing obligation on the part of regulated entities to improve safety. Not only did Congress keep in place the prohibitions against adulteration and misbranding, even for products that had received premarket approval, but it also added provisions designed to ensure post-market vigilance in matters of safety. See, *e.g.*, 21 U.S.C. § 360h(e) (authorizing FDA to recall devices); 21 U.S.C. § 360h(e)(1)(B) (requiring notification to doctors and hospitals of dangerous devices); 21 U.S.C. § 360*l* (establishing requirements for post-market surveillance). These provisions demonstrate Congress's understanding that the premarket approval process sets a minimum standard for regulated products, one that sometimes proves inadequate in light of subsequent consumer and market experience. Preservation of state-based tort claims is a complement, not an affront, to this statutory scheme.

Third, the Food, Drug, and Cosmetic Act regulated medical devices long before the Medical Device Amendments of 1976. The 1938 enactment added the category of "device" to the products regulated under the Act. See *United States v. Article of Drug . . . Bacto-Unidisk*, 394 U.S. 784, 796-797 (1969). Under this statute, the prohibitions against adulteration and misbranding were applied to medical devices. *Id.* at 797; Federal Food, Drug, and Cosmetic Act of 1938, Pub. L. No 75-71, § 301(a), 52 Stat. 1040, 1042. Thus medical devices became subject to the same protections against dangerousness and deception that had long been applied to foods and drugs.

The 1938 statute did not, however, apply the process of premarket safety review to devices. The absence of a requirement of premarket safety approval, combined with

the recognition of the strong public health purposes of the Act, persuaded this Court to extend the premarket approval requirements applicable to drugs to items that, in truth, looked a lot more like devices than drugs. In *Bacto-Unidisk*, the Court held that devices used in the laboratory to test the sensitivity of certain microorganisms to certain antibiotics (aptly called "antibiotic sensitivity discs") were "drugs" and thus were subject to the Act's requirements for premarket safety review. 394 U.S. at 793-798. Although the discs never touched a patient's body, the Court thought that the Act's "overriding purpose to protect the public health" counseled in favor of broad construction of the Act. *Id.* at 798. The practical effect of the Court's ruling was to subject the antibiotic sensitivity discs to the same premarket approval process applied to drugs. The decision in *Bacto-Unidisk* is of a piece with other decisions from this Court recognizing "the high purpose of the Act" in protecting consumers. *Kordel v. United States*, 335 U.S. 345, 349 (1948).

Fourth, state-based tort claims have peacefully co-existed with the federal regulatory framework for many decades. Foods and drugs regulated by the Food, Drug, and Cosmetic Act remained subject to state-based common law claims not only in the period between 1906 and 1938, when the federal requirements applicable to them were the prohibitions on adulteration and misbranding. See, *e.g.*, *Mazetti v. Armour & Co.*, 75 Wash. 622 (Wash. 1913); *Moehlenbrock v. Parke, Davis & Co.*, 141 Minn. 154 (Minn. 1918); *Hruska v. Parke, Davis & Co.*, 6 F.2d 536 (8th Cir. 1925); *Machlitt v. Myers*, 23 Ohio App. 160 (Ohio App. 1926); *Coca Cola Bottling Works v. Selvidge*, 4 Tenn. App. 558 (Tenn. App. 1927); *Ritchie v. Sheffield Farms Co.*, 222 N.Y.S. 724 (N.Y. Mun. Ct. 1927); *Abbott Labs. v. Lapp*, 78 F.2d 170 (7th Cir. 1935). Drugs also remained subject to tort claims even after 1938, when Congress added the provisions creating a premarket review process for drugs. See, *e.g.*, *Wennerholm v. Stanford Univ. Sch.*

*of Med.*, 128 P.2d 522 (Cal. 1942); *Wechsler v. Hoffman-La Roche, Inc.*, 99 N.Y.S.2d 588 (N.Y. Sup. 1950); *Berry v. Am. Cyanamid Co.*, 341 F.2d 14 (6th Cir. 1965); *Sterling Drug, Inc. v. Cornish*, 370 F.2d 82 (8th Cir. 1966); *Love v. Wolf*, 58 Cal. Rptr. 42 (Cal. Ct. App. 1967); *Krug v. Sterling Drug, Inc.*, 416 S.W.2d 143 (Mo. 1967); *Toole v. Richardson-Merrell Inc.*, 60 Cal.Rptr. 398 (Cal. Ct. App. 1967); *Fritz v. Parke Davis & Co.*, 277 Minn. 210 (Minn. 1967); *Williams v. Vick Chemical Co.*, 279 F. Supp. 833 (S.D. Iowa 1967); *Bine v. Sterling Drug, Inc.*, 422 S.W.2d 623 (Mo. 1968); *Davis v. Wyeth Labs., Inc.*, 399 F.2d 121 (9th Cir. 1968); *Sterling Drug, Inc. v. Yarrow*, 408 F.2d 978 (8th Cir. 1969); *Tinnerholm v. Parke, Davis & Co.*, 411 F.2d 48 (2d Cir. 1969); *Parke-Davis & Co. v. Stromsodt*, 411 F.2d 1390 (8th Cir. 1969); *Grinnell v. Charles Pfizer & Co.*, 79 Cal.Rptr. 369 (Cal. Ct. App. 1969); *Kershaw v. Sterling Drug, Inc.*, 415 F.2d 1009 (5th Cir. 1969); *Schenebeck v. Sterling Drug, Inc.*, 423 F.2d 919 (8th Cir. 1970); *Hornung v. Richardson-Merrill, Inc.*, 317 F. Supp. 183 (D. Mont. 1970); *Croft v. York*, 244 So.2d 161 (Fla. App. 1971); *Singer v. Sterling Drug, Inc.*, 461 F.2d 288 (7th Cir. 1972); *Stevens v. Parke, Davis & Co.*, 507 P.2d 653 (Cal. 1973); *Redfield v. Mead, Johnson & Co.*, 266 Or. 273 (Or. 1973); *Hoffman v. Sterling Drug, Inc.*, 374 F. Supp. 850 (M.D. Pa. 1974); *Reyes v. Wyeth Labs.*, 498 F.2d 1264 (5th Cir. 1974); *Crocker v. Winthrop Labs., Div. of Sterling Drug, Inc.*, 514 S.W.2d 429 (Tx. 1974); *McEwen v. Ortho Pharm. Corp.*, 270 Or. 375 (Or. 1974); *Whitley v. Cubberly*, 210 S.E.2d 289, (N.C. Ct. App. 1974); *Oresman v. G. D. Searle & Co.*, 388 F. Supp. 1175 (D. R.I. 1975); *Henry v. Richardson-Merrell, Inc.*, 508 F.2d 28 (3d Cir. 1975); *Salmon v. Parke, Davis & Co.*, 520 F.2d 1359 (4th Cir. 1975). Of course, this is only a partial list of the actual cases; in particular, the list stops at 1975. This end date has a substantive objective: the listed cases were all on the books when Congress enacted the Medical Device Amendments of 1976. If Congress wanted to avoid the history of tort litigation that had accompanied drugs even after the creation of the premarket review process in 1938, one would have

expected a different statement than the one provided in the preemption provision Congress chose.

When medical devices were added to the statutory mix in 1938, they, too, remained subject to state-based tort claims. In fact, in the ensuing decades, courts entertained many tort suits relating to medical devices. See, *e.g.*, *Orthopedic Equip. Co. v. Eutsler*, 276 F.2d 455 (4th Cir. 1960) (upholding jury ruling in favor of plaintiff in action against manufacturer of surgical nail); *Vergott v. Deseret Pharm. Co.*, 463 F.2d 12 (5th Cir. 1972) (upholding tort-based jury verdict against manufacturer of needle used for catheter, which broke off in plaintiff's vein); *Dreiling v. Gen. Elec. Co.*, 511 F.2d 768 (5th Cir. 1975) (upholding jury verdict for defendant in case involving allegedly defective pacemaker); *Cinocca v. Baxter Lab.*, 400 F. Supp. 527 (E.D. Okla. 1975) (denying summary judgment to corporate successor of firm that manufactured allegedly defective heart valve); *E.R. Squibb & Sons., Inc. v. Jordan*, 254 So.2d 17 (Fla. App. 1971) (remanding for new trial on question whether beef bone processed and marketed by defendant and used in spinal operation was defective); *Friedman v. Medtronic, Inc.*, 345 N.Y.S.2d 637 (NY App. Div. 1973) (jury verdict for plaintiff, alleging breach of implied warranty with respect to pacemaker, overturned on appeal).

Indeed, the tort system itself played no small part in galvanizing support for the very 1976 amendments alleged to preempt relief in this case. In the early 1970s, reports emerged about serious safety problems associated with medical devices. Most famously, thousands of women who used the Dalkon Shield were injured by it, and some died. S. Rep. 94-33, at 6 (1975), 94 Cong. 2d Sess., *as reprinted in* 1976 U.S.C.C.A.N. 1070. Lawsuits sprang up all over the country, to such an extent that eventually a multidistrict panel on litigation was convened to deal with the numerous claims. *In*

*re A. H. Robbins Co., Inc. "Dalkon Shield" IUD Prod. Liab. Litig.*, 406 F. Supp. 540 (J.P.M.L. 1975). In 1976, in the midst of this episode, Congress passed the Medical Device Amendments - without so much as a whisper suggesting that the Dalkon Shield lawsuits (or the many other lawsuits that had been brought relating to medical devices) might be undone by the statute it had passed. *Lohr*, 518 U.S. at 490-491 & n. 13.

Fifth, this Court's decisions construing the Act have respected, even celebrated, the protective purposes of the statute. The Act, Justice Frankfurter wrote in 1943, touches "phases of the lives and health of people which, in the circumstances of modern industrialism, are largely beyond self-protection. Regard for these purposes should infuse construction of the legislation if it is to be treated as a working instrument of government and not merely as a collection of English words." *Dotterweich*, 320 U.S. at 280. At the same time, the Court has underscored the Act's goal of encouraging continuous efforts to improve safety by holding corporate officials responsible for dangers within their reach: "[I]n providing sanctions which reach and touch the individuals who execute the corporate mission . . . the Act imposes not only a positive duty to seek out and remedy violations when they occur but also, and primarily, a duty to implement measures that will insure that violations will not occur." *United States v. Park*, 421 U.S. 658, 672 (1975). Acknowledging that "[h]ardship there doubtless may be" under such a system, the Court has recognized that Congress chose to place the hardship "upon those who have at least the opportunity of informing themselves of the existence of conditions imposed for the protection of consumers before sharing in illicit commerce, rather than to throw the hazard on the innocent public who are totally helpless." *Dotterweich*, 320 U.S. at 284-285. The application of tort law to matters embraced by the Act is fully consistent with the Act's large purpose of promoting responsible

commerce. In truth, it would be a deep irony if this same statute were held to displace one of the few avenues consumers have to engage in self-help against irresponsible commerce - state-based common law.

In sum, a finding that tort law remains as a complement to the regulatory framework of the Food, Drug, and Cosmetic Act is perfectly consistent with - and indeed, congenial to - the history and structure of the statute as a whole.

**II. This Court's Recent Rulings On Preemption Must Be Understood With Reference To The Specific Regulatory Settings In Which They Arose.**

This Court has long recognized that federal preemption of state laws related to health and safety is a delicate matter. Indeed, the Court has frequently invoked "the assumption that the historic police powers of the States were not to be superseded by [federal statute] unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

This solicitousness toward state protections of health and safety is evident in the modern regulatory era. In *Silkwood v. Kerr-McGee Corp.*, the Court held that a claim for punitive damages relating to the operation of a facility that made plutonium fuel pins was not preempted by the Atomic Energy Act. 464 U.S. 238, 258 (1984). Based on a painstaking analysis of the text and history of the relevant federal statutes, the Court found that Congress had all along assumed that state tort law would remain viable even in the midst of the massive federal regulatory regime applicable to nuclear facilities. *Id.* at 248-258.

Likewise, in *Cipollone v. Liggett Group, Inc.*, the Court meticulously scrutinized the textual differences between the Federal Cigarette Labeling and Advertising Act of 1965 and the Public Health Cigarette Smoking Act of 1969 in coming to its conclusion that the latter statute, but not the former, preempted some common law claims. 505 U.S. 504, 518-524 (1992). The Court further scrutinized the 1969 statute in order to figure out precisely which common law claims had been preempted. *Id.* at 524-531. Based on a close reading of the statutory text, the Court found that failure-to-warn claims were preempted, but claims based on breach of express warranty and fraudulent misrepresentation were not. *Ibid.*

The Court's decision in *Cipollone* has been regarded by some observers as a watershed moment in preemption history, insofar as it appears to be the first case in which this Court held that a federal statute preempted a state products liability claim even where the federal law provided no individual remedy of its own. See David Owen, *Federal Preemption of Products Liability Claims*, 55 S.C. L. REV. 411, 423 (2003). In addition, the Court's reading of the 1969 statute's language of "requirements" to include state common law claims inspired fear that the decision presaged a large-scale turn away from the Court's traditional reluctance to set aside state laws protecting health and safety. And indeed, this concern appeared well founded when *Cipollone* spurred a whole new wave of preemption litigation. See David C. Vladeck, *Preemption and Regulatory Failure*, 33 PEPP. L. REV. 95, 106 (2005). Nevertheless, a close reading of the decision reveals the Court doing the work it has always done in preemption cases: assiduously comparing the allegedly preemptive federal statute with the specific state-law claims being pressed.

This narrower understanding of the implications of *Cipollone* has been validated by subsequent decisions of this Court. The Court's next major pronouncement on the relationship between an allegedly preemptive federal law and a state tort claim came in the context of the same statute at issue here. In *Medtronic, Inc. v. Lohr*, 518 U.S. 470, the Court held that the Medical Device Amendments did not - despite their use of the term "requirements," the interpretation of which had led to such a ruckus following *Cipollone* - preempt state common-law claims based on negligent design, manufacturing, and labeling. 518 U.S. 470, 501-503 (1996).

In *Lohr*, the plurality came within a whisker of holding that the Medical Device Amendments simply did not preempt tort claims at all, but refrained from deciding the question conclusively because it was not necessary to dispose of the case. 518 U.S. at 502-503. In preserving the tort claims at issue there, the Court found that "generic concerns about device regulation generally" were not the sorts of federal "requirements" that would lead to preemption under the statute, *id.* at 501, and that general state common-law claims likewise were "not the kinds of requirements that Congress and the FDA feared would impede the ability of federal regulators to implement and enforce specific federal requirements." *Ibid.* The Court in *Lohr* was, above all else, concerned with actual inconsistencies between federal and state requirements, not with an abstract potential for tension.

The same preference for the specific statutory language and intent over abstract possibilities carried the day in the Court's unanimous decision in *Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002). In construing the express preemption provision in the Federal Boat Safety Act, the Court found it "perfectly rational for Congress not to pre-empt common-law claims, which - unlike most administrative and

legislative regulations - necessarily perform an important remedial role in compensating accident victims." *Id.* at 64. The Court also found that the Coast Guard's general declination to set propeller guard standards for boats was perfectly consistent "with a tort verdict premised on a jury's finding that some type of propeller guard should have been installed on this particular kind of boat equipped with respondent's particular type of motor." *Id.* at 67.

Even more telling is the Court's recent decision in *Bates v. Dow Agroscience LLC*, 544 U.S. 431 (2005). While holding that the word "requirements" in the preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) referred to at least some state-based common law claims, the Court also held that the fact that the provision preempted "judge-made rules, as well as statutes and regulations, says nothing about the *scope* of that preemption." *Id.* at 443-444. The Court narrowed the class of common-law claims that might be preempted by FIFRA by focusing on the statutory phrases qualifying the word "requirements." *Id.* at 444. In addition, the Court narrowed even the scope of what might be regarded as "requirements" by excluding tort principles that merely induced particular action on the part of pesticide manufacturers:

> A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement. The proper inquiry calls for an examination of the elements of the common-law duty at issue; it does not call for speculation as to whether a jury verdict will prompt the manufacturer to take any particular action (a question, in any event, that will depend on a variety of cost/benefit calculations best left to the manufacturer's accountants).

*Id.* at 445 (citation omitted).

Even where the Court found that the common-law claims at issue in *Bates* fell within the statutory definition of "requirements," the Court found that they were not preempted if they "were equivalent to, and fully consistent with," the federal provisions. *Id.* at 447. Here, the Court called upon statutory language strikingly similar to that contained in the Medical Device Amendments, and found that it preserved state-law claims so long as they were parallel to federal requirements. *Id.* at 447-448 (relying on *Lohr*, 518 U.S. at 495).

Significantly, the Court in *Bates* found support for its ruling in "the long history of tort litigation against manufacturers of poisonous substances." *Id.* at 449. The Court thought that this history not only "emphasizes the importance of providing an incentive to manufacturers to use the utmost care in the business of distributing inherently dangerous items," *id.* at 450, but that it also made it "unlikely" that Congress used a "relatively obscure provision" to erase this traditional liability. *Id.* at 450. The Court also thought that tort liability could "aid, rather than hinder," the operation of the federal statute, particularly since the statute contemplated that the pesticide labels governed by the statute "will evolve over time." *Id.* at 451.

The cases relevant here are, in short, both complex and pragmatic. The cases are complex as a result of the Court's salutary insistence on digging deep into the details of the putatively preemptive federal scheme and comparing them to the details of the putatively preempted state laws. The cases are pragmatic insofar as they are alert to the way in which Congress is likely to express an intent to displace state law. The Court's decision in *Bates* is especially instructive on the latter point, as the Court thought it improbable that

Congress would subtly undo a long history of state-based tort litigation.

The appeals court's decision in this case shows none of the subtlety and pragmatism that characterize this Court's preemption cases. In place of complex and concrete analysis of exactly how the federal law on medical devices relates to the tort claims at issue here, the court offered generalized anxiety about the abstract potential for conflict between the federal and state schemes. *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 121-123 (2d Cir. 2006). And in place of a realistic appraisal of how Congress is likely to express an intent to displace longstanding tort principles, the court vaguely opined that "it is much less clear" that these principles survived creation of the premarket review process for the most dangerous medical devices. *Id.* at 123.

**III. The Medical Device Amendments Do Not Preempt The Petitioners' Tort Claims.**

Petitioners' brief explains in detail why petitioners' tort claims survive the narrow preemption provision of the Medical Device Amendments, 21 U.S.C. § 360k(a). We adopt these arguments. In this closing section, we highlight several points that might not stand out in petitioners' comprehensive discussion of the relevant issues.

First, this case is very different from *Cipollone*. There, the federal statute dictated the contents of the labels on cigarette packages. Cigarette makers were not allowed to deviate from those mandates. Here, in contrast, the FDA simply approved an application developed and submitted by Medtronic. Approval without specific, prescriptive conditions is not a "requirement"; it is more a dispensation than a dictate. Nothing in the FDA's approval required Medtronic to manufacture or distribute a defective device,

inadequately labeled. Even if the FDA had listed some conditions of approval, generic common-law duties and remedies such as the duty of care and the duty to warn would not conflict with those device-specific conditions.

Second, the preceding point highlights the lack of conflict here between the federal and state frameworks. Medtronic was not required, to borrow Justice Breyer's formulation from his partial concurrence in *Lohr*, to use the catheter-equivalent of a two-inch wire, 518 U.S. at 503-508, and petitioners' prayer for tort relief asks for nothing inconsistent with the FDA's approval of Medtronic's catheter. If petitioners prevailed on their tort claims, Medtronic would not be caught in a bind between federal and state compliance. This case thus does not present the potential for conflict that concerned Justice Breyer in *Lohr*. Indeed, it bears noting that Medtronic no longer even makes the Evergreen Balloon Catheter. In this case, even a potential for tension between federal law and state remedies is nonexistent.

Third, the criterion for premarket approval of medical devices itself points to the contingent and preliminary nature of the FDA's decision, reinforcing our earlier point that the premarket approval process is complemented by post-market controls, including tort law. The standard for approval of medical devices is "reasonable assurance" of safety. 21 U.S.C. § 360e(d)(2)(A), (B). The hopeful but tentative nature of this standard appears to assume the availability of the kind of post-market discipline embodied in tort-based remedies. See *also* 21 U.S.C. 306h(d) (offset provision regarding economic damages recovered under federal or state law, embodying background assumption of tort liability).

Fourth, the abundant tort actions relating to medical devices entertained by the courts prior to 1976 parallel the long history of tort litigation relating to poisonous substances, emphasized by this Court in *Bates*. 544 U.S. at 449-450. Here, as there, it is improbable that Congress would undo these longstanding remedies with a provision that does not even mention the common law. Equally telling is the rich history of litigation relating to drugs, discussed in Part I above, following the creation of the premarket review process for drugs. If Congress had wanted, in creating the premarket review process for medical devices, to avoid the tort litigation that had for decades complemented the premarket review process for drugs, it is reasonable to expect that it would have said so in plain terms.

Every day in this country, consumers must trust strangers to provide them with uncontaminated food, good medicine, honest financial services, safe cars, and the whole host of other products and services associated with modern life. Congress has passed a wide variety of laws aimed at promoting a fair and safe marketplace. Longstanding principles of tort, such as the duty of care and the duty to warn, are fixed on the same goal, albeit with the added aim of compensating victims of wrongful conduct. It has been, and should continue to be, the most unusual case when this Court upends the friendly collaboration between federal laws and state tort remedies. This is not that case.

## CONCLUSION

The judgment of the court of appeals should be reversed.

Respectfully submitted,

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August 27, 2007

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34 No. 06-179

IN THE

# Supreme Court of the United States

DONNA S. RIEGEL, individually and as administrator of the estate of Charles R. Riegel,
*Petitioner*,

v.

MEDTRONIC, INC.,
*Respondent*.

**On Writ of Certiorari to the United States Court of Appeals for the Second Circuit**

## BRIEF OF CROPLIFE AMERICA, AMERICAN CHEMISTRY COUNCIL, AND CONSUMER SPECIALTY PRODUCTS ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT


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TABLE OF CONTENTS


| | Page |
|---|---|
| TABLE OF AUTHORITIES | ii |
| INTEREST OF THE *AMICI CURIAE* | 1 |
| SUMMARY OF ARGUMENT | 3 |
| ARGUMENT | 6 |
| I. MANUFACTURERS ARE NOT IMMUNIZED FROM PRODUCT LIABILITY SUITS BY EXPRESS PREEMPTION OF DAMAGES CLAIMS THAT ARE PREMISED UPON STATE-LAW DUTIES WHICH DIVERGE FROM FEDERAL REQUIREMENTS | 6 |
| II. CONSUMER PROTECTION IS ENHANCED BY EXPRESS PREEMPTION OF DAMAGES CLAIMS THAT ARE PREMISED UPON STATE-LAW DUTIES WHICH DIVERGE FROM FEDERAL REQUIREMENTS | 12 |
| III. THE "PARALLEL REQUIREMENTS" EXCLUSION SHOULD APPLY ONLY TO DAMAGES CLAIMS THAT ARE PREMISED UPON BREACH OF A SPECIFIC STATE-LAW DUTY TO COMPLY WITH A SPECIFIC FEDERAL REQUIREMENT | 21 |
| CONCLUSION | 29 |

## TABLE OF AUTHORITIES


CASES — Page

*Aetna Health Inc. v. Davila*, 542 U.S. 200 (2004) ..... 11

*Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.*, 959 F.2d 158 (10th Cir.), *vacated and remanded*, 506 U.S. 910 (1992) (vacating and remanding for further consideration in light of *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)), *previous opinion adhered to*, 981 F.2d 1177 (10th Cir.), *cert. denied*, 510 U.S. 813 (1993) ..... 16

*Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005) ..... *passim*

*Booth v. Board of Regents*, No. Civ.A. 7:05-CV-34, 2005 WL 2099246 (M.D. Ga. Aug. 30, 2005) ..... 23

*Central Valley Fresh Produce, Inc. v. Wilbur-Ellis Company*, No. 04 CE CG 00542 (Cal. Super. Ct., Fresno Cty. June 30, 2005) (unpublished) ..... 23

*Chicago & North Western Transporation Company v. Kalo Brick & Tile Company*, 450 U.S. 311 (1981) ..... 11

*Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) ..... 4, 8, 19

*Etcheverry v. Tri-Ag Service, Inc.*, 993 P.2d 366 (Cal. 2000) ..... 11, 16

*Ferebee v. Chevron Chemical Company*, 736 F.2d 1529 (D.C. Cir. 1984) ..... 16

*Geier v. American Honda Motor Company*, 529 U.S. 861 (2000) ..... 19, 20

*Grenier v. Vermont Log Buildings, Inc.*, 96 F.3d 559 (1st Cir. 1996) ..... 11

TABLE OF AUTHORITIES—Continued

Page

*King v. E. I. DuPont de Nemours & Company*, 996 F.2d 1346 (1st Cir. 1993).. 16

*Kuiper v. American Cyanamid Company*, 131 F.3d 656 (7th Cir. 1997)..... 11

*Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996).....*passim*

*Mortellite v. Novartis Crop Protection, Inc.*, 460 F.3d 483 (3rd Cir. 2006)..... 12

*National Bank of Commerce v. Dow Chemical Company*, 165 F.3d 602 (8th Cir. 1999)..... 11

*Netland v. Hess & Clark, Inc.*, 284 F.3d 895 (8th Cir. 2002)..... 11

*Papas v. Upjohn Company*, 926 F.2d 1019 (11th Cir. 1991), *vacated and remanded sub nom. Papas v. Zoecon Corp.*, 505 U.S. 1215 (1992) (vacating and remanding for further consideration in light of *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992)), *aff'd sub nom. Papas v. Upjohn Co.*, 985 F.2d 516 (11th Cir.), *cert. denied*, 510 U.S. 913 (1993)..... 16

*Riegel v. Medtronic, Inc.*, 451 F.3d 104 (2d Cir. 2006).....*passim*

*United States v. Locke*, 529 U.S. 89 (2000).. 25

*Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597 (1991).....15, 17, 18

*Worm v. American Cyanamid Company*, 5 F.3d 744 (4th Cir. 1993)..... 28

*Wuebker v. Wilbur-Ellis Company*, 418 F.3d 883 (8th Cir. 2005)..... 12

TABLE OF AUTHORITIES—Continued

STATUTES AND REGULATIONS


| | Page |
|---|---|
| 7 U.S.C. § 136(q)(1)(G) | 26 |
| 7 U.S.C. § 136v(a) | 17 |
| 7 U.S.C. § 136v(b) | *passim* |
| 21 U.S.C. § 360k(a) | *passim* |
| 21 C.F.R. § 808.1(d)(1) | 24 |
| 40 C.F.R. Part 156 | 22 |


MISCELLANEOUS


| | |
|---|---|
| H.R. Rep. No. 92-511 (1971), *reprinted in* 1972 U.S.C.C.A.N. 3993 | 17 |
| NORMAN J. SINGER, J.D. SHAMBIE SINGER, STATUTES AND STATUTORY CONSTRUCTION § 46.6 (7th ed. 2007) | 22 |

IN THE

# Supreme Court of the United States

No. 06-179

DONNA S. RIEGEL, individually and as administrator of the estate of Charles R. Riegel,
*Petitioner*,

v.

MEDTRONIC, INC.,
*Respondent.*

**On Writ of Certiorari to the United States Court of Appeals for the Second Circuit**

## BRIEF OF CROPLIFE AMERICA, AMERICAN CHEMISTRY COUNCIL, AND CONSUMER SPECIALTY PRODUCTS ASSOCIATION AS *AMICI CURIAE* IN SUPPORT OF RESPONDENT

## INTEREST OF THE *AMICI CURIAE* [1]

*Amici curiae* CropLife America, American Chemistry Council, and Consumer Specialty Products

[1] The parties have consented to the filing of this brief. No counsel for a party authored this brief in whole or in part, and no counsel or party made a monetary contribution intended to fund the preparation or submission of this brief. No person other than *amici curiae*, their members, or their counsel made a monetary contribution to its preparation or submission.

Association are submitting this brief because they have a substantial interest in the development, interpretation, and application of this Court's jurisprudence on federal preemption of state-law damages claims involving products whose safety is closely regulated by expert federal agencies such as the Food and Drug Administration (FDA) and the United States Environmental Protection Agency (EPA). *Amici* believe that consumer protection is significantly strengthened by preemption of any type of tort claim that is based on a state-law duty which diverges from, conflicts with, or otherwise undermines federal safety regulation, especially in areas such as product labeling and warnings, where nationally uniform regulation is critical to proper usage.

CropLife America is the national trade association for the plant science industry. Its member companies develop, produce, sell, and distribute virtually all of the agricultural crop protection pesticides and biotechnology products used by American farmers to provide consumers with safe, affordable, and abundant food and fiber. For more than sixty years CropLife America has been industry's leading voice on significant federal and state pesticide regulatory issues. One such issue is the deleterious impact of state-law failure-to-warn claims on the system of nationally uniform product labeling which Congress mandated through enactment of § 136v(b) of the Federal Insecticide, Fungicide, and Rodenticide Act ("FIFRA"), 7 U.S.C. § 136v(b). CropLife America has participated as *amicus curiae* in numerous appeals involving the scope of FIFRA preemption under § 136v(b), including *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005), a case upon which petitioner and the *amici curiae* supporting her heavily rely.

The American Chemistry Council represents the leading companies engaged in the business of chemistry. A substantial number of the Council's members produce and distribute pesticides, including a wide variety of antimicrobial products, which like all pesticide products, are comprehensively regulated under FIFRA by EPA.

The Consumer Specialty Products Association represents the interests of companies which provide households, institutions, and industrial customers with products that help provide a cleaner and healthier environment. Those products include disinfectants and insecticides used in homes, hospitals, and restaurants.

## SUMMARY OF ARGUMENT

1. Petitioner and her *amici curiae* are attempting to use this premarket approval ("PMA") medical device product liability case as a vehicle for mounting an all-out assault on the principle, firmly established by this Court's federal preemption precedents, that state-law damages claims can be encompassed by a federal regulatory statute's express prohibition against state-imposed requirements. Their anti-preemption policy arguments, which present a lopsided view of the benefits of product liability litigation, mistakenly assume that manufacturers are totally immunized from liability by express preemption confined to damages claims that are based on state-law duties which diverge from federal regulatory requirements regarding safety-related subjects such as product design or labeling. They also incorrectly assume that such express preemption—although limited in scope—deprives persons injured by defective

products of their sole means for obtaining compensation.

2. Petitioner's theory that *no* damages claim can be encompassed by a federal statute's preemption provision unless Congress has manifested an unequivocal intent to preempt *any and all* damages claims not only is illogical, but also contrary to the claim-by-claim framework for express preemption analysis mandated by this Court's precedents, such as *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), and *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005). In reaffirming this claim-by-claim approach, which the Second Circuit followed here in applying § 360k(a) of the Food, Drug, and Cosmetic Act's Medical Device Amendments ("MDA"), 21 U.S.C. § 360k(a), the Court should make it clear that the substance and elements of a state-law cause of action, and not the name a plaintiff assigns to a particular claim, determines whether it falls within the scope of a federal statute's express preemption provision.

3. Consumer protection is enhanced, not undermined, by federal preemption of damages claims that would impose state-law duties which diverge from or otherwise conflict with federal regulatory requirements. This is especially true where a federal statute's goal is to achieve national uniformity of regulation regarding product design, labeling, or other safety-related subjects. Conflicting or differing jury verdicts, which indisputably have a regulatory effect on a product's manufacturer, can impede, impair, or destroy the national uniformity that Congress seeks to achieve under the auspices of expert and experienced federal agencies such as FDA and EPA.

4. In opposing preemption of state-law damages claims, petitioner and her *amici* rely too much on flawed dicta in the *Bates* majority opinion, which addresses the preemptive scope of § 136v(b) of FIFRA. In particular, the history of prior tort litigation is irrelevant to the plain meaning of a preemption provision such as § 136v(b) of FIFRA or § 360k(a) of the MDA. Tort claims that impose divergent state-law duties can seriously disrupt federal regulatory programs. And the majority's suggestion that product liability litigation is the only means for obtaining compensation seems oblivious to corporate social responsibility and product stewardship programs which voluntarily compensate consumers when and if post-market problems develop.

5. The Court should clarify that the inferential "parallel requirements" exclusion from express preemption discussed in *Bates* and *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), should not be applied in a way which nullifies congressional intent to preempt state requirements that are different from or in addition to federal requirements. A broad exclusion which encompasses any general common-law duty that is consistent with any general federal statutory standard would provide plaintiffs and their attorneys with a virtually automatic route around express preemption. Instead, the exclusion should apply only if a claim is based on a specific state-law duty that seeks to enforce a specific federal regulatory requirement.

## ARGUMENT

### I. MANUFACTURERS ARE NOT IMMUNIZED FROM PRODUCT LIABILITY SUITS BY EXPRESS PREEMPTION OF DAMAGES CLAIMS THAT ARE PREMISED UPON STATE-LAW DUTIES WHICH DIVERGE FROM FEDERAL REQUIREMENTS

In its opinion below, the court of appeals took "care to explain that [it did] not hold that all state tort claims as to PMA-approved devices are preempted." *Riegel v. Medtronic, Inc.*, 451 F.3d 104, 106 (2d Cir. 2006). The lower court further indicated that "contrary to the dissent's fear that the decision . . . will deprive those who were injured by an unreasonably dangerous medical device of any remedy whatsoever . . . the scope of [the] decision is actually quite limited." *Id.* at 124 (internal quotation marks omitted). Nevertheless, petitioner's wide-ranging attack on federal preemption of state-law damages claims involving federally regulated products approaches that subject as if it were an all-or-nothing proposition. Her arguments against preemption are predicated upon the mistaken notion that either Congress manifestly intended to afford *total* immunity to manufacturers of allegedly defective, federally regulated products, thereby depriving consumers of all judicial recourse, or such manufacturers necessarily are subject to the full panoply of state-law causes of action for product liability regardless of the plain, broad language of a federal statute's preemption provision.

Relying upon this "total immunity" fallacy, petitioner asserts that the issue before the Court is whether a manufacturer such as Medtronic "is entitled to immunity from state-law damages suits,

regardless of their merits, the nature of Medtronic's conduct, or the severity of the resulting injuries." Pet. Br. at 14; *see also id.* at 1 (referring to "Medtronic's plea for immunity from liability"). Petitioner's *amici* follow the same tack.[2] Taking aim at this overblown target, petitioner argues that there is a "glaring absence in the legislative record of any suggestion that consumers would lose their only means of obtaining compensation for injuries." Pet. Br. at 19. She urges the Court to equate the lack of congressional intent to afford manufacturers blanket immunity from product liability suits with the opposite extreme, namely, that "Congress did not intend § 360k(a) to preempt damages claims at all." *Id.* at 15.

Petitioner's black-or-white approach to federal preemption of product liability litigation conflicts with the type of careful, claim-by-claim analysis which this Court repeatedly has indicated courts must follow when applying a federal regulatory statute's express preemption provision to damages suits. In analyzing the preemptive scope of § 5(b) of the Public Health Cigarette Smoking Act of 1969, which provides that "[n]o requirement or prohibition based on smoking and health shall be imposed under State law with respect to the advertising or promotion of any

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[2] *See, e.g.*, Br. of AARP at 21 (arguing against "immunizing device manufacturers from tort suits"); Br. of Sen. Kennedy & Rep. Waxman at 8 ("Congress did not intend to preempt state tort suits."); Br. of Am. Ass'n for Justice at 8 ("The question before the Court is whether Congress intended [the MDA] to prevent future victims from bringing state-law tort actions . . . ."); Br. for the States of New York, *et al.* at 4-5 ("It is simply implausible that Congress . . . would have meant to supersede all of state tort law in the area of device safety.").

cigarettes," the Court in *Cipollone v. Liggett Group, Inc.*, explained why a claim-by-claim analysis is necessary:

> That the pre-emptive scope of § 5(b) cannot be limited to positive enactments *does not mean that that section pre-empts all common law claims*. . . . For purposes of § 5(b), the common-law is not of a piece.
>
> Instead . . . we must look to each of petitioner's common-law claims to determine whether it is in fact pre-empted.

505 U.S. at 523 (emphasis added). The Court then proceeded to consider whether § 5(b) of the Cigarette Act applied to each type of state-law damages claim alleged in the suit (e.g., failure to warn; breach of express warranty; fraudulent misrepresentation). *Id.* at 523-30; *see* Br. of Consumers Union at 3, 12 ("This Court's precedents on preemption dictate a close analysis of both the purportedly preemptive federal law and the purportedly preempted state rule. . . . a close reading of the [*Cipollone*] decision reveals the Court doing the work it has always done in pre-emption cases: assiduously comparing the allegedly preemptive federal statute with the specific state-law claims being pressed.").

The court of appeals adhered to this claim-by-claim analytical framework in applying § 360k(a) of the MDA to this case. First, the lower court, 451 F.3d at 114-16, discussed this Court's fragmented express preemption decision in *Medtronic, Inc. v. Lohr*, which in part V of the lead opinion analyzed the applicability of § 360k(a) to each of Medtronic's different types of claims, *see* 518 U.S. at 492-94 (discussing design claim) and *id.* at 497-502 (discussing manufacturing and labeling claims). The court then considered the

causes of action in this case, and concluded that some—but not all—tort claims involving PMA medical devices are expressly preempted by § 360k(a). *See Riegel*, 451 F.3d at 124 ("[T]ort claims that are premised on a manufacturer's deviation from the standards set forth in the device's approved PMA application . . . are in no way preempted. Only those claims that allege liability despite a PMA-approved device's adherence to those standards are . . . preempted.").

The Court should affirm the Second Circuit's holding, which concludes that § 360k(a) expressly preempts many types of state-law claims, *see id.* at 121, but neither immunizes medical device manufacturers from damages suits, nor deprives consumers of judicial recourse for non-preempted causes of action, *id.* at 123 (agreeing "with the district court's conclusion that the Riegels' negligent manufacturing claim was not preempted"). None of this Court's product liability preemption precedents, including *Bates v. Dow AgroSciences*, mandates or condones the wholesale approach to tort preemption that petitioner is advocating here (i.e., that *no* tort claims are preempted unless Congress deliberately and demonstrably intended to enact a provision that preempts *all* tort claims).

In *Bates*, a product liability suit involving a federally regulated pesticide, the Court reiterated its holding in both *Cipollone* and *Lohr* that an express preemption provision which prohibits states from imposing their own requirements "reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties," 544 U.S. at 443, but that such a proscription does *not* afford manufacturers blanket immunity from product liabil-

ity suits. The Court indicated instead that to determine whether a particular claim is preempted, "[t]he proper inquiry calls for an examination of the elements of the common-law duty at issue." *Id.* at 445 (citing *Cipollone*, 505 U.S. at 524).

More specifically, *Bates* holds, based on the express terms of § 136v(b) of FIFRA, that "a particular state rule" is preempted only if it satisfies two conditions: "First, it must be a requirement *'for labeling or packaging*,'" and "[s]econd, it must impose a labeling or packaging requirement that is *'in addition to or different from* those required under [FIFRA].'" *Id.* at 444 (quoting 7 U.S.C. § 136v(b)).[3] Applying the first prong of this test for express preemption under FIFRA, the Court held that unlike "fraud and negligent failure-to-warn claims," which "are premised on common-law rules that qualify as 'requirements for labeling or packaging,'" *id.* at 446, "petitioners' claims for defective design, defective manufacture, negligent testing, and breach of express warranty are not preempted," *id.* at 444, because "[n]one of these common-law rules requires that manufacturers label or package their products in any particular way," *ibid.*

This Court's classification of different types of damages claims as falling either within or outside the scope of a statute's express preemption provision should not relieve a trial court of the task of analyzing each cause of action pleaded in a particular suit to determine whether it is preempted. For example,

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[3] Both the MDA and FIFRA contain "a similarly worded preemption provision." *Bates*, 544 U.S. at 447. Each preempts "any" state-imposed "requirements" that are "in addition to" or "different from" federal requirements. *Compare* 21 U.S.C. § 360k(a) and 7 U.S.C. § 136v(b).

prior to *Bates* numerous courts recognized that the applicability of § 136v(b) of FIFRA does not depend upon "the guise under which the claim is presented." *Netland v. Hess & Clark, Inc.*, 284 F.3d 895, 900 (8th Cir. 2002);[4] *see generally Aetna Health Inc. v. Davila*, 542 U.S. 200, 214 (2004) ("[D]istinguishing between pre-empted and non-pre-empted claims based on the particular label affixed to them would elevate form over substance and allow parties to evade the pre-emptive scope of [the statute] simply by relabeling their . . . claims." (internal quotation marks omitted); *Chicago & North Western Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 324 (1981) (preemption cannot be "avoided by mere artful pleading"). Along the same lines, Justice Thomas' separate opinion in *Bates*, joined by Justice Scalia, explains that "[a] state-law cause of action, *even if not specific to labeling*, nevertheless imposes a labeling requirement 'in addition to or different from' FIFRA's when it attaches liability to statements on the label that do not produce liability under FIFRA." *Bates*, 544 U.S.

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[4] *See, e.g., Nat'l Bank of Commerce v. Dow Chem. Co.*, 165 F.3d 602, 608 (8th Cir. 1999) ("It is immaterial whether an inadequate labeling or failure to warn claim is brought under a negligence or products liability theory."); *Kuiper v. American Cyanamid Co.*, 131 F.3d 656, 662 (7th Cir. 1997) (holding that § 136v(b) preempts claims for misrepresentation or express warranty based on oral or advertising statements "if they merely repeat information in the label itself"); *Grenier v. Vermont Log Bldgs., Inc.*, 96 F.3d 559, 565 (1st Cir. 1996) (holding that § 136v(b) preempts a purported design or manufacturing defect claim if it is actually a "disguised labeling claim"); *Etcheverry v. Tri-Ag Serv., Inc.*, 993 P.2d 366, 377 (Cal. 2000) ("When a claim, however couched, boils down to an assertion that a pesticide's label failed to warn of the damage plaintiff allegedly suffered, the claim is preempted by FIFRA.").

at 456 (emphasis added) (Thomas, J. concurring in the judgment in part and dissenting in part). But subsequent to the Court's seemingly rigid listing of non-preempted categories of claims in *Bates*, courts in pesticide-related suits have been acting reflexively, declining to look behind the name that a plaintiff assigns to a cause of action to determine whether it is based on a rule that qualifies as a requirement for labeling, and thus is preempted.[5] In affirming the Second Circuit's medical device preemption decision here, the Court should clarify *Bates*, and indeed emphasize that form does not trump substance when determining whether a state-law product liability claim, no matter how denominated, is expressly preempted by a federal regulatory statute such as the MDA or FIFRA.

## II. CONSUMER PROTECTION IS ENHANCED BY EXPRESS PREEMPTION OF DAMAGES CLAIMS THAT ARE PREMISED UPON STATE-LAW DUTIES WHICH DIVERGE FROM FEDERAL REQUIREMENTS

Petitioner and her *amici* repeatedly assert that federal preemption of damages claims undermines

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[5] *See, e.g., Mortellite v. Novartis Crop Protection, Inc.*, 460 F.3d 483, 490 (3rd Cir. 2006) ("FIFRA does not preempt claims based on theories of strict liability, negligent testing, and breach of express warranty. As the Supreme Court explained, such common law claims plainly do not impose labeling requirements . . . ."); *Wuebker v. Wilbur-Ellis Co.*, 418 F.3d 883, 887 (8th Cir. 2005) (rejecting, based on *Bates*, manufacturer's contention that plaintiffs' defective design and breach of warranty claims, "as pleaded," challenge the adequacy of FIFRA labeling requirements).

consumer protection. They contend that product liability litigation against manufacturers of federally regulated products is an essential and beneficial form of supplemental, state-by-state regulation necessitated by "constrained and conflicted" federal agencies. Br. of AARP at 6.[6] Further, they contend that preemption of damages claims "would improperly foreclose all remedies," Pet. Br. at 43, thereby depriving injured persons of their sole financial recourse.[7]

To the contrary, consumer protection is *enhanced* when highly experienced federal agencies, staffed by dedicated scientific experts, regulate products such as medical devices, drugs, and pesticides in a nationally uniform manner. Product liability claims based on state-law duties that diverge from or otherwise conflict with federal requirements can have a significant adverse impact on national uniformity of regulation concerning safety-related subjects such as product design and label warnings. Furthermore, the vast majority of manufacturers display a high degree

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[6] *See also* Br. of Am. Ass'n for Justice at 15 (referring to "the longstanding reliance on post-marketing liability as a complementary means to achieve product safety"); Br. of Consumers Union at 18 ("It has been, and should continue to be, the most unusual case when this Court upends the friendly collaboration between federal laws and state tort remedies."); Br. of AARP at 7 ("The limited PMA process . . . is entirely inadequate to replace the long-standing safety incentives and consumer protections provided by state tort law.").

[7] *See also* Pet. Br. at 19 (referring to the "absence in the legislative record of any suggestion that consumers would lose their only means of obtaining compensation for injuries caused by poorly designed or inadequately labeled PMA devices"); Br. of AARP at 27 ("Tort law provides the only relief for patients injured by defective medical devices.").

of corporate responsibility by voluntarily compensating consumers when and if safety-related problems develop with their products.

In proffering their objections to *any* federal preemption of damages claims, petitioner and her *amici* place too much reliance upon policy dicta included within Justice Stevens' majority opinion in *Bates*. As Justice Thomas, joined by Justice Scalia, indicated in his partial dissent,

> the majority [opinion] advances several arguments *designed to tip the scales in favor of the States* and against the Federal Government. These arguments, in addition to being *unnecessary*, are *unpersuasive*. . . . [O]ur task is to determine which state-law claims [the statute] pre-empts, without slanting the inquiry in favor of either the Federal Government or the States.

*Bates*, 544 U.S. at 457 (Thomas, J., concurring in the judgment in part and dissenting in part) (emphasis added).

1. The *Bates* majority opinion asserts that the "long history of tort litigation against manufacturers . . . adds force to the basic presumption against preemption." 544 U.S. at 449. Justice Thomas, joined by Justice Scalia, disagreed:

> The history of tort litigation against manufacturers is . . . *irrelevant*. . . . We cannot know, without looking to the text of § 136v(b), whether FIFRA preserved that tradition or displaced it. . . . [W]hile allowing additional state-law remedies likely aids in enforcing FIFRA's misbranding requirements . . . it is for Congress, not this Court, to strike a balance between state tort suits and federal regulation.

*See id.* at 457-58 (Thomas, J.) (emphasis added).[8] In the case of FIFRA, even if "tort litigation against pesticide manufacturers . . . was a common feature of the legal landscape at the time of the 1972 amendments," *id.* at 440-41, that ancient history is completely irrelevant. This is because "the extensive amendments" that Congress adopted in 1972, *id.* at 437, which were "spurred by growing environmental and safety concerns," *ibid.*, included "significantly strengthen[ing] FIFRA's . . . labeling standards," *Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 601 (1991), in part by enacting § 136v(b). The purpose of § 136v(b) is to achieve and maintain national labeling uniformity by prohibiting states from imposing "requirements for labeling" that are "in addition to or different from" federal requirements. *See Bates*, 544 U.S. at 452.

Along the same lines, it is not surprising that a "groundswell of federal and state decisions" holding that certain types of tort claims are expressly preempted by a statutory prohibition against state-imposed "requirements," *Bates*, 544 U.S. at 441, did not emerge until after the Court's *Cipollone* opinion in 1992. Indeed, the Court triggered the wave of FIFRA tort preemption decisions when, within a week of deciding *Cipollone*, it vacated and remanded two FIFRA cases for further consideration in light of *Cipollone*. After both courts of appeals held on remand, based on *Cipollone*, that § 136v(b) expressly

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[8] Justices Thomas and Scalia have expressed the view that the presumption against preemption "does not apply . . . when Congress has included within a statute an express pre-emption provision." *Bates*, 544 U.S. at 457 (Thomas, J.) (citing *Cipollone*, 505 U.S. at 545-46) (Scalia, J., concurring in judgment in part and dissenting in part)).

preempts labeling-related damages claims, the Court declined further review,[9] and during the next twelve years denied certiorari in many other FIFRA preemption cases prior to granting review in *Bates*. Further, as the Court noted in *Bates*, 544 U.S. at 441, prior to *Cipollone*, only the D.C. Circuit had considered the question of whether damages claims are encompassed by § 136v(b), and contrary to this Court's subsequent holdings in *Cipollone*, *Lohr*, and *Bates*, held that the term "requirements" is limited to state positive enactments.[10]

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[9] *See Arkansas-Platte & Gulf Partnership v. Van Waters & Rogers, Inc.*, 959 F.2d 158 (10th Cir.), *vacated and remanded*, 506 U.S. 910 (1992) (vacating and remanding for further consideration in light of *Cipollone*), *previous opinion adhered to*, 981 F.2d 1177 (10th Cir.), *cert. denied*, 510 U.S. 813 (1993); *Papas v. Upjohn Co.*, 926 F.2d 1019 (11th Cir. 1991), *vacated and remanded sub nom. Papas v. Zoecon Corp.*, 505 U.S. 1215 (1992) (vacating and remanding for further consideration in light of *Cipollone*), *aff'd sub nom. Papas v. Upjohn Co.*, 985 F.2d 516 (11th Cir.), *cert. denied*, 510 U.S. 913 (1993).

[10] The *Bates* majority opinion's invocation of that pre-*Cipollone* decision, *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529 (D.C. Cir. 1984), is puzzling. *See Bates*, 544 U.S. at 451. In the wake of *Cipollone*, numerous courts of appeals and state appellate courts have held that *Ferebee* "is no longer good law." *Etcheverry v. Tri-Ag Serv.*, 993 P.2d at 372; *see, e.g., King v. E. I. DuPont de Nemours & Co.*, 996 F.2d 1346, 1351 (1st Cir. 1993) ("In deciding *Ferebee*, the District of Columbia Circuit did not have the benefit of the Supreme Court's subsequent analysis and ruling in *Cipollone* . . . we do not find *Ferebee* persuasive."). Moreover, the D.C. Circuit "has expressly acknowledged that *Cipollone* repudiated [*Ferebee*'s] central premise by 'explaining that damage actions . . . must be preempted where positive enactments are preempted.'" *Etcheverry*, 993 P.2d at 372 (quoting *Waterview Management Co. v. F.D.I.C.*, 105 F.3d 696, 699 (D.C. Cir. 1997)).

2. The *Bates* majority opinion denigrates the crucial role that national uniformity of regulation plays in promoting the safety of products such as medical devices, drugs, and pesticides. *See* 544 U.S. at 450 (asserting that the "United States greatly overstate[d] the degree of uniformity and centralization that characterizes FIFRA"). In the case of FIFRA, the fact that "the statute authorizes a relatively decentralized scheme that preserves a broad role for state regulation," *ibid.*, proves nothing about the statute's express preemption of divergent state *labeling* requirements. Congress mandated, through enactment of § 136v(b)—which is entitled "Uniformity"—that EPA establish and maintain a system of nationally uniform product labeling. To be sure, the statute preserves the states' supplemental role in regulating pesticide "sale or use." *See* 7 U.S.C. § 136v(a). But when Congress "transformed FIFRA . . . into a comprehensive regulatory statute," *Mortier*, 501 U.S. at 601 (internal quotation marks omitted), it did *not* "authorize[] a relatively decentralized scheme," *Bates*, 544 U.S. at 450, with regard to product labeling, which this Court acknowledges is "an area that FIFRA's [federal-state regulatory] 'program' pre-empts," *Mortier*, 501 U.S. at 615.[11]

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[11] Legislative materials demonstrate that when Congress enacted § 136v(b) in 1972 (four years prior to § 360k(a) of the MDA), it believed that EPA alone—and not the states—would have authority to regulate pesticide labeling. *See, e.g.*, H.R. Rep. No. 92-511 (1971) at 16 ("In dividing the responsibility between the States and the Federal Government for the management of an effective pesticide program, the [House] Committee [on Agriculture] has adopted language which is *intended to completely preempt State authority in regard to labeling.*") (emphasis added). Along the same lines, in *Mortier*, the Court explained that "FIFRA's historic focus [is] on labeling," 501 U.S.

Pesticide labeling is different from the ordinary labels placed on most types of non-federally regulated products. It enables EPA, a federal agency which possesses tremendous scientific expertise and decades of regulatory experience, to ensure that all necessary warnings, safety precautions, directions for use, and other essential information are communicated from a pesticide product's manufacturer through the chain of distribution to the individuals who actually use the product. The substantial health, safety, environmental, and product performance benefits that nationally uniform, EPA-regulated product labeling affords to consumers, farmers, and professional pesticide applicators cannot be overstated. The same undoubtedly is true for nationally uniform medical device and drug labeling.

The *Bates* majority opinion acknowledges the "narrow, but still important, role" that § 136v(b) plays in the FIFRA scheme: "In the main, it pre-empts competing state labeling standards—imagine 50 different labeling regimes prescribing the color, font size, and wording of warnings . . . ." 544 U.S. at 452. Further, the opinion holds that § 136v(b) expressly preempts "any statutory or common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA and its implementing regulations." *Ibid.* Yet, the opinion asserts that the United States, which appeared in *Bates* as *amicus curiae*, "exaggerate[d] the disruptive effects of using common-law suits to enforce the prohibition on misbranding," *id.* at 451.

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at 613, and that when Congress rewrote FIFRA in 1972, it "significantly strengthened" the Act's "labeling standards," *id.* at 601, in part by enacting § 136v(b).

To the contrary, where as in the case of the MDA or FIFRA, national uniformity with respect to a particular regulated subject such as labeling is an undeniable statutory objective, *especially* where that goal is expressed in a plainly and broadly worded preemption provision and is not constrained by a saving clause, damages claims that encroach upon the federal regulatory scheme necessarily conflict with congressional intent and threaten to destroy uniformity. Where "the pre-emption provision itself reflects a desire to subject the industry to a single, uniform set of federal safety standards . . . [t]his policy by itself favors pre-emption of state tort suits, for the rules of law that judges and juries create or apply in such suits may themselves similarly create uncertainty and even conflict, say, when different juries in different States reach different decisions on similar facts." *Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 871 (2000).

In the same vein, petitioner concedes that § 360k(a) of the MDA was enacted to supplant state regulation and achieve nationwide uniformity, *see* Pet. Br. at 7, 16, but fails to reconcile that important, safety-related statutory objective with this Court's repeated holding that damages awards are a form of state regulation. *See, e.g., Cipollone*, 505 U.S. at 521. Even if, as petitioner asserts, "the impetus for Congress's enactment of a preemption provision [in the MDA] was the existence of state regulatory programs that potentially could subject device manufacturers to inconsistent requirements once federal requirements were put into place," Pet. Br. at 16, it would be illogical to assume that Congress would have wanted to allow the states to circumvent preemption and impose such inconsistent requirements through dam-

ages awards. *See Lohr*, 518 U.S. at 504 (Breyer, J., concurring in part and concurring in the judgment) (discussing the "anomalous consequences" of failing to recognize that "[t]he effects of the state agency regulation and the state tort suit are identical"). As the court of appeals explained below, in the absence of preemption "it is certainly conceivable that different juries would reach conflicting verdicts about the same medical devices, thus rendering it almost impossible for a device to comply simultaneously with its federal PMA (which, after all, can only change after an extensive process) and with the various verdicts issued by different juries around the country." *Riegel*, 451 F.3d at 122. This Court should affirm the opinion below "to avoid the conflict, uncertainty, cost, and occasional risk to safety itself that too many different safety-standard cooks might otherwise create." *Geier*, 529 U.S. at 871.

3. The *Bates* majority opinion erroneously suggests that "depriv[ing] injured parties of a long available form of compensation," 544 U.S. at 449, would eliminate their only recourse. That proposition is necessarily incorrect where, as in the case of the MDA and FIFRA, an express preemption clause is limited in scope, and thus does not cloak a manufacturer with blanket immunity from product liability suits. Further, the premise that litigation is the only way to obtain compensation for defective products simply is not true. Most companies that market federally regulated products such as medical devices, drugs, and pesticides are responsible corporate citizens and seek to avoid litigation by voluntarily compensating persons legitimately claiming to have been injured by their products.

For example, as a matter of good product stewardship and sound business sense, agricultural pesticide manufacturers, through their regional and local representatives, work closely with individual farmers to investigate and resolve pesticide-related problems, such as crop injury. When circumstances warrant, manufacturers voluntarily provide a variety of remedies such as cost reimbursement, pesticide reapplication, replacement of seed, or monetary compensation. In the infrequent event of widespread problems, manufacturers establish formal claims resolution programs to try to learn more about the claims and avoid the costs and burdens of litigation for the benefit of all parties and the public.

## III. THE "PARALLEL REQUIREMENTS" EXCLUSION SHOULD APPLY ONLY TO DAMAGES CLAIMS THAT ARE PREMISED UPON BREACH OF A SPECIFIC STATE-LAW DUTY TO COMPLY WITH A SPECIFIC FEDERAL REQUIREMENT

As an alternative to their contention that "Congress did not intend § 360k(a) to preempt damages claims at all," petitioner asserts "that, if § 360k(a) is nonetheless read to encompass damages claims, such preemption would occur only in very narrow circumstances." Pet. Br. at 15-16. Indeed, in part III of her brief, *id.* at 39, petitioner attempts to transform the "parallel" state requirements exclusion from preemption discussed in *Bates*, 544 U.S. at 447-48, and *Lohr*, 518 U.S. at 494-97, 513 (O'Connor, J., concurring in part and dissenting in part), into a *gaping loophole* which would swallow any preemption provision that prohibits states from imposing their own, additional or different regulatory requirements, either through positive enactments or damages awards. In affirm-

ing the opinion below, the Court should make it clear that the "parallel requirements" exclusion discussed in *Bates* and *Lohr* should not be applied in a way that renders express preemption provisions meaningless. *See generally* NORMAN J. SINGER, J.D. SHAMBIE SINGER, STATUTES AND STATUTORY CONSTRUCTION § 46.6 (7th ed. 2007) ("A statute should be construed so that effect is given to all of its provisions, so that no part will be inoperative or superfluous, void or insignificant . . . .").

In *Bates* the Court, finding "strong support" in *Lohr*, adopted a "'parallel requirements' reading of § 136v(b)" that excludes "a state-law labeling requirement . . . if it is equivalent to, and fully consistent with, FIFRA's misbranding provisions." 544 U.S. at 447. The Court indicated that "[s]tate-law requirements must also be measured against any relevant EPA regulations that give content to FIFRA's misbranding standards." *Id.* at 453; *see, e.g.*, 40 C.F.R. Part 156 (Labeling Requirements for Pesticides). Thus, the Court held that § 136v(b) "pre-empts any statutory or common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA and its implementing regulations," but "[i]t does not . . . pre-empt any state rules that are fully consistent with federal requirements." *Id.* at 452. The Court stressed that although "the state-law requirement need not be phrased in the *identical* language as its corresponding FIFRA requirement . . . If a case proceeds to trial, the court's jury instructions must ensure that nominally equivalent labeling requirements are *genuinely* equivalent." *Id.* at 454.

Seizing upon the "parallel requirements" language in *Bates* and *Lohr*, petitioner contends that "the

Riegels' claims are not preempted for the additional reason that they are based on duties that mirror federal design and labeling requirements." Pet. Br. at 39. Petitioner contends that all it takes to avoid an otherwise broadly stated express preemption provision (e.g., a preemption provision prohibiting states from imposing requirements that are different from or in addition to federal requirements) is a state-law claim that is based on a *general* common-law duty (e.g., the duty to provide adequate warnings) and a similarly general federal statutory standard or requirement (e.g., the duty to distribute a product that is not misbranded). *See id.* at 42.[12] According to petitioner, "[s]tate damages claims are ordinarily premised on duties of general applicability, such as the duty to warn of risks or to use due care in the design of a product," *id.* at 38, and such common-law duties escape preemption because they are "equivalent to the federal standards." *Id.* at 14.[13]

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[12] Like petitioner, some trial courts have read *Bates* as requiring only the most superficial type of comparison to conclude that a state-law failure-to-warn or fraud claim, although premised on state-law requirements for labeling, falls outside the scope of § 136v(b) of FIFRA. *See, e.g., Booth v. Bd. of Regents*, No. Civ.A. 7:05-CV-34, 2005 WL 2099246, at *3 (M.D. Ga. Aug. 30, 2005) ("In this case, the requirements that would be imposed by the Georgia law of fraud are consistent with FIFRA."); *Central Valley Fresh Produce, Inc. v. Wilbur-Ellis Co.*, No. 04 CE CG 00542 (Cal. Super. Ct., Fresno Cty. June 30, 2005) ("[H]ere plaintiff's claims of inadequate warnings or instructions on the product label appear to be consistent with FIFRA's misbranding provisions, since the statute expressly forbids false or misleading statements on a product as well as inadequate instructions or warnings.").

[13] Damages claims based on general common-law duties purporting to be applicable to federally regulated medical devices

For example, petitioner asserts that any medical device-related inadequate warning claim arising under New York law falls outside the scope of § 360k(a) of the MDA because "[t]he generally applicable New York state-law duty to warn mirrors [the] general federal requirement" prohibiting the marketing of a "misbranded" medical device. *Id.* at 42. Similarly, petitioner argues that because New York law relating to the duty to design reasonably safe products "states these obligations very generally . . . a state determination, through a damages verdict, that a device was not reasonably safe is consistent with the federal scheme." *Id.* at 40.

To be sure, this Court held in *Lohr* and *Bates* that even a broad federal statutory prohibition against states imposing their own, "different" or "additional" requirements through damages claims does not encompass identical, parallel, equivalent, or fully consistent state requirements. In *Bates* the Court left it to the court of appeals to determine, on remand, whether the "particular common-law duties" underlying the petitioners' fraud and failure-to-warn claims "are equivalent to FIFRA's misbranding standards," 544 U.S. at 447, "emphasiz[ing] that a state-law labeling requirement must in fact be equivalent to a requirement under FIFRA in order to survive preemption," *id.* at 453.

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should not be confused with FDA's regulatory exemption from preemption for state "requirements of general applicability where the purpose of the requirement relates . . . to *other products* in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code . . . )." 21 C.F.R. § 808.1(d)(1) (emphasis added).

According to petitioner's expansive view of the parallel requirements exclusion, however, virtually every product liability claim involving a federally regulated product is based on a general common-law duty that is equivalent to a general federal statutory standard, and therefore, no product liability claim ever would impose a state-law requirement that is "different from" or "in addition to" a federal regulatory requirement, and thus, be expressly preempted. If such a facile comparison of general common-law tort duties (e.g., the duty to warn) with general federal statutory requirements (e.g., the requirement to ensure that products are not misbranded) were sufficient to save damages claims from preemption, the congressional allocation of regulatory authority between the Federal Government and the states reflected in the terms of an express preemption provision such as § 360k(a) of the MDA or § 136v(b) of FIFRA would be rendered meaningless. *Cf. United States v. Locke*, 529 U.S. 89, 106 (2000) ("We decline to give broad effect to saving clauses where doing so would upset the careful regulatory scheme established by federal law.").

The Court, therefore, should reject petitioner's wholesale attempt to circumvent express preemption of damages claims by means of the parallel requirements exclusion. Instead, to give meaning to *both* express preemption of additional or different state requirements and the implicit exclusion for parallel requirements, the Court should clarify *Lohr* and *Bates* by holding that the exclusion applies only to damages claims premised upon a manufacturer's alleged breach of a state-law duty to comply with a *specific federal requirement*. "While States are free to impose liability predicated on a *violation of the*

*federal standards* set forth in FIFRA and in any accompanying regulations . . . they may not impose liability for labeling requirements predicated on *distinct state standards* of care." *Bates*, 544 U.S. at 455 (Thomas, J., concurring the judgment in part and dissenting in part) (emphasis added).

For example, in holding that § 360k(a) does not preempt petitioner's defective manufacturing claim, the court of appeals indicated that "[a] jury verdict in the Riegels' favor on this claim would not have imposed state requirements that differed from, or added to, the *PMA-approved standards* for this device, but would instead have simply sought recovery for Medtronic's alleged deviation from those standards." *Riegel*, 451 F.3d at 123 (emphasis added). Or, in the FIFRA context, a state-law claim alleging that a pesticide manufacturer failed to include on product labeling a *specific* warning that was *required by EPA* would be based on a state-law duty that is "*genuinely* equivalent" to the federal requirement, *Bates*, 544 U.S. at 454; *see also id.* at 442 ("Nothing in the text of FIFRA would prevent a State from making the violation of a *federal* labeling or packaging requirement a state offense, thereby imposing its own sanctions on pesticide manufacturers who violate federal law.") (emphasis added).[14]

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[14] Further, because a pesticide label containing all warnings required under FIFRA would not be misbranded for lack of adequate warnings, *see* 7 U.S.C. § 136(q)(1)(G), a failure-to-warn claim concerning that pesticide necessarily would impose state-law requirements for labeling that are in addition to or different from the federal requirements, and therefore, would be expressly preempted. *See Bates*, 544 U.S. at 454 ("For a manufacturer should not be held liable under a state labeling require-

But a damages claim premised upon noncompliance with a specific state-law duty that parallels a specific federal requirement (such as a federal design or labeling specification) is quite unlike a product liability claim premised upon breach of a general common-law duty to design reasonably safe products or to provide adequate labeling and warnings. The "liability-creating premise" for the latter type of claim "is that the [product] itself, in its present [federally] approved form, is in some way defective and therefore requires modification." *Riegel*, 451 F.3d at 122. This type of claim should not be allowed to automatically escape a federal regulatory statute's express preemption of additional or different, state-imposed requirements merely because it is based on a general state-law duty that is consistent with a general federal regulatory standard or requirement.

Thus, a damages claim premised upon failure to design a medical device in a way that differs from the device's FDA-approved design, including any specific FDA design requirements, would be preempted by § 360k(a) even though the general common-law duty to design reasonably safe products is consistent with the general MDA requirement that the safety and effectiveness of the device be reasonably assured. *Cf. Lohr*, 518 U.S. at 503-04 (Breyer, J., concurring in part and concurring in the judgment) (discussing, by way of example, why a claim based on failure to design a hearing aid component with a 1-inch wire would be preempted if FDA regulations require a 2-inch wire). Similarly, a claim based on a manufacturer's failure to provide pesticide label warnings

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ment subject to § 136v(b) unless the manufacturer is also liable for misbranding as defined by FIFRA.").

that go beyond those required by EPA would be based on a "common-law rule that would impose a labeling requirement that diverges from those set out in FIFRA and its implementing regulations," *Bates*, 544 U.S. at 452, and would be expressly preempted by § 136v(b) even though the state common-law duty to provide adequate warnings is consistent with FIFRA's prohibition against misbranding.[15]

The vast majority of manufacturers go to great lengths to ensure compliance with all requirements pertaining to the design, safety, labeling, and sale of their federally regulated products. While the parallel requirements exclusion would enable a damages claim to avoid preemption in the event of a manufacturer's noncompliance with specific federal design, labeling, or other requirements, this Court should not allow it to function as a readily accessible means for flouting congressional intent.

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[15] In one of the leading pre-*Bates* cases on FIFRA preemption, *Worm v. American Cyanamid Co.*, 5 F.3d 744 (4th Cir. 1993), the court of appeals held that § 136v(b) permits "a state . . . to recognize that a breach of a *FIFRA-created duty* forms the basis for a state remedy," but that "[a]llowing such actions . . . is substantially distinguishable from accepting the argument that the state common law duty to warn is not 'in addition to or different from' the federally defined duty." *Id.* at 748 (emphasis added).

## CONCLUSION

The judgment of the court of appeals should be affirmed.

Respectfully submitted,

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IN THE

# Supreme Court of the United States

CHARLES R. RIEGEL AND DONNA S. RIEGEL,

*Petitioners,*

v.

MEDTRONIC, INC.,

*Respondent.*

**On Writ of Certiorari to the United States Court of Appeals for the Second Circuit**

## BRIEF OF SENATOR EDWARD M. KENNEDY AND REPRESENTATIVE HENRY A. WAXMAN, AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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## TABLE OF CONTENTS

TABLE OF AUTHORITIES ..... ii

INTEREST OF *AMICI CURIAE* ..... 1

HISTORY OF THE MEDICAL DEVICE AMENDMENTS OF 1976 AND ITS PREEMPTION PROVISION. ..... 2

A. The Federal Food, Drug, and Cosmetic Act. ..... 2

B. The 1976 Medical Device Amendments. ..... 4

C. The MDA's Preemption Provision. ..... 6

D. The *Lohr* Decision. ..... 6

SUMMARY OF ARGUMENT ..... 8

ARGUMENT ..... 9

THE LANGUAGE OF THE MDA AND ITS LEGISLATIVE HISTORY DEMONSTRATE THAT CONGRESS DID NOT INTEND TO PREEMPT STATE COMMON LAW TORT SUITS ..... 9

CONCLUSION ..... 21

## TABLE OF AUTHORITIES

**Page(s)**

**Cases:**

*Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005) ..... 10, 15, 19

*Chisom v. Roemer*, 501 U.S. 380 (1991) ..... 16

*Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) ..... 7, 9, 10, 18

*Commissioner v. Lundy*, 516 U.S. 235 (1996) ..... 14

*Edmondson v. International Playtex, Inc.*, 678 F. Supp. 1571 (N.D. Ga. 1987) ..... 17

*English v. General Electric Co.*, 496 U.S. 72 (1990) ..... 9

*Gustafson v. Alloyd Co., Inc.*, 513 U.S. 561 (1995) ..... 15

*Ignace v. International Playtex, Inc.*, No. 86-C-480-C, 1987 WL 93996 (W.D. Wis. Aug. 14, 1987) ..... 16

*Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) ..... *passim*

*Muzatko v. International Playtex, Inc.*, No. 85-C-1540, 1987 U.S. Dist. LEXIS 14281 (E.D. Wis. May 14, 1987) ..... 17

*Palmer v. Liggett Group, Inc.*, 633 F. Supp. 1171 (D. Mass. 1986) ..... 17

*Roysdon v. R.J. Reynolds Tobacco Co.*, 623 F. Supp. 1189 (E.D. Tenn. 1985) ..... 17

*Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85 (1983) ..... 9

*Sullivan v. Stroop*, 496 U.S. 478 (1990) ..... 15

*United States Department of Treasury v. Fabe*, 508 U.S. 491 (1993) ..... 14

**Statutes and Bills:**

Animal Drug Amendments of 1968, Pub. L. No. 90-399, 82 Stat. 343 (codified as amended at 21 U.S.C. § 382).....10

Color Additive Amendments of 1960, Pub. L. No. 86-618, 74 Stat. 399 (codified as amended at 21 U.S.C. § 376).....10

Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (codified as amended at 21 U.S.C. § 321, *et seq.)*.....10

21 U.S.C. § 321(h).....5

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Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended at 21 U.S.C. § 360c, *et seq.)*.....1, 4

21 U.S.C. § 360c(a)(1)(B).....6

21 U.S.C. § 360c(a)(1)(C).....5

21 U.S.C. § 360d.....12

21 U.S.C. § 360(e)(b)(1).....5

21 U.S.C. § 360e(c)(1).....5

21 U.S.C. § 360e(d)(1)(B)(ii).....12

21 U.S.C. § 360e(e)(1).....20

21 U.S.C. § 360e(e)(2).....20

21 U.S.C. § 360i.....12

21 U.S.C. § 360i(a).....5

21 U.S.C. § 360j(e) ..... 12

21 U.S.C. 360j(f) ..... 5

21 U.S.C. § 360k(a) ..... *passim*

21 U.S.C. § 360k(b) ..... *passim*

21 U.S.C. § 379r ..... 17

21 U.S.C. § 379s(a) ..... 18

21 U.S.C. § 379s(d) ..... 18

Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (codified as amended at 15 U.S.C §§ 1331, *et seq.)* ..... 7, 14

15 U.S.C. § 1331 ..... 15

15 U.S.C. §§ 1331-40 ..... 8

Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 76 (1906) ..... 2

S. 510, 94th Cong. (1975) ..... 1

1970 Cal. Stat. 3270 ..... 13

**Regulations and Federal Register Notices**:

21 C.F.R. § 801.410 ..... 11

21 C.F.R. § 801.430 ..... 17

21 C.F.R. § 808.1(b) ..... 16

21 C.F.R. § 808.5(b)(2) ..... 17

21 C.F.R. § 808.53 ..... 6

21 C.F.R. § 808.55 ..... 6

21 C.F.R. § 808.69 ..... 6

21 C.F.R. § 860.3(c)(3) ..... 5

21 C.F.R. § 874.3300(b)(2) ..... 5

42 Fed. Reg. 30383 (June 14, 1977)..... 16

43 Fed Reg. 18661 (May 2, 1978)..... 16

**Legislative Materials**:

121 Cong. Rec. S6140 (Apr. 17, 1975)..... 5

H.R. Rep. No. 94-853 (1976)..... *passim*

Hearing on H.R. 5545 Before the House Subcommittee on Health and the Environment of the Committee on Interstate and Foreign Commerce, 94th Cong. 1 (1975)..... 5

S. Rep. No. 94-33 (1975)..... 4

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Brief of the United States as Amicus Curiae *Lohr v. Medtronics, Inc.*, 518 U.S. 470 (1996)..... 19

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Lyndon, Mary, *Tort Law and Technology*, 12 Yale J. on Reg. 137 (1995) ..... 20

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Rheingold, Paul D., *The MER/29 Story—An Instance of Successful Mass Disaster Litigation*, 56 Cal. L. Rev. 116 (1968) ..... 10

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Vladeck, David A., *Preemption and Regulatory Failure*, 33 Pepp. L. Rev. 95 (2005) ..... 21

## INTEREST OF *AMICI CURIAE*[1]

Edward M. Kennedy has been a member of the United States Senate representing the State of Massachusetts since 1962. Senator Kennedy currently serves as Chairman of the Senate Committee on Health, Education, Labor and Pensions. In 1974-76, as the Chairman of the Subcommittee on Health, Labor and Public Welfare, Senator Kennedy held hearings on legislation to strengthen FDA's authority over medical devices and was the sole sponsor of the Senate bill (S. 510) that resulted in the passage of the Medical Device Amendments of 1976, Pub. L. No. 94-295, 90 Stat. 539 (codified as amended at 21 U.S.C. § 360c, *et seq.*) ("MDA") to the Federal Food, Drug and Cosmetic Act ("FFDCA"), 21 U.S.C. § 301, *et seq.*

Representative Henry A. Waxman has been a member of the United States House of Representatives representing the 30th Congressional District of the State of California since 1974. Representative Waxman currently serves as Chairman of the House Government Reform and Oversight Committee, which has investigative authority over all government agencies and areas of federal policy. In 1976, Congressman Waxman served on the House Committee on Interstate and Foreign Commerce, which reported out the MDA legislation. Congressman Waxman supported the MDA and actively participated in the debates on the legislation.

Senator Kennedy and Congressman Waxman have dedicated their careers to working on public health issues, and over the past 30 years have sponsored numerous bills related to the Food and Drug Administration ("FDA") that have been

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[1] Petitioners and respondent have filed letters with the Clerk of the Court consenting to the submission of amicus curiae briefs in this action. Pursuant to Rule 37.6, *amici* state that no counsel for a party authored this brief in whole or in part. No person or entity other than *amici* and their counsel made a monetary contribution to the preparation or submission of the brief.

enacted into law. They seek leave to file this brief because they believe that the decision of the United States Court of Appeals for the Second Circuit is contrary to the legislative purpose and intent of the MDA, and that it stands as a significant obstacle to the fulfillment of the important policy objectives that underscored the passage of that law.

## HISTORY OF THE MEDICAL DEVICE AMENDMENTS OF 1976 AND ITS PREEMPTION PROVISION.

### A. The Federal Food, Drug, and Cosmetic Act.

For over a century, the FDA has been responsible for protection of the public health with regard to the use of a wide range of medical and other consumer products. Its authorizing statute, the Federal Food, Drug and Cosmetic Act, 21 U.S.C. § 301, *et seq.*, has been frequently amended as emerging science and new technology have created a need for greater or evolving protections. Often, Congress has enacted these amendments in the wake of a public health crisis.

Enacted in 1938, the FFDCA itself was passed in the wake of the elixir sulfanilamide disaster.[2] Elixir sulfanilamide was an untested sulfa drug that caused the deaths of nearly 100 people, many of them children. The statute for the first time required pre-marketing approval for drugs, mandating that drug manufacturers demonstrate safety before a new drug could be marketed to the public. Congress, however, did not enact a corresponding pre-market approval requirement for medical devices.

In some instances where Congress has amended the FFDCA to address a public health crisis, product liability

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[2] The Pure Food and Drugs Act of 1906, Pub. L. No. 59-384, 34 Stat. 768, was the first federal statute regulating pharmaceuticals. It did not require pre-market approval of drugs and focused on preventing the sale of misbranded and adulterated products.

lawsuits brought by the victims of defective products helped bring the problem to the attention of Congress, as was true when Congress adopted the MDA. Despite repeated references to such lawsuits in legislative history, however, Congress never has expressed any intention to preempt such litigation in any of the amendments to the Act. In fact, the MDA is the first time that Congress included a specific preemption provision in the FFDCA, and, as *amici* explain below, that provision was included to address a specific state legislative scheme for regulating medical devices and not to preempt product liability lawsuits against device manufacturers. At the time the MDA was enacted in 1976, the terminology used in the preemption provision was understood by Congress not to encompass product liability litigation.

While FDA had focused earlier on protecting the public from fraudulent claims made for bogus devices, around 1960 FDA began focusing on health hazards created by legitimate medical devices. H.R. Rep. No. 94-853 ("House Report") at 7. Emerging technology drove this effort: the creation of heart pacemakers, kidney dialysis machines, defibrillators, cardiac and renal catheters, surgical implants and other complicated diagnostic and therapeutic devices heightened the potential harm for consumers. *Id.* In 1969, the Secretary of Health, Education and Welfare convened a medical device study group, chaired by Theodore Cooper, M.D., then-director of the National Heart and Lung Institute ("the Cooper Committee"). *Id.* at 9.

The Cooper Committee held meetings with representatives of the medical profession, industry, consumers and government agencies, and it conducted an extensive literature search that identified 10,000 injuries from medical devices over a 10-year period, of which 751 resulted in death. *Id.* The Committee recommended that new legislation be targeted specifically to the device industry, because devices presented entirely different issues from drugs. It also suggested that different classifications for medical devices be

created, which would tailor the regulatory controls to the risks involved.

**B. The 1976 Medical Device Amendments.**

While the Cooper Committee's recommendations were being debated in Congress during 1972 and 1973, pacemaker failures became widely reported. Between 1972 and 1976, there were 34 voluntary recalls of pacemakers involving 23,000 units. *Id.* at 8. In 1975, Congress held hearings to investigate problems that had been reported with the Dalkon Shield intrauterine device.

As the House Report on the bill noted, the FFDCA's "inadequacy has become a matter of acute concern because of the rapid technological advances in the medical device field." *Id.* at 11. The Report also found that "[a]bsent clear, statutory authority to regulate medical devices, the FDA cannot safeguard the health of the American public by assuring the safety and effectiveness of such products." *Id.* at 12

The tragedy of the Dalkon Shield, which caused spontaneous abortions, uterine infections, and many deaths, played an important role in the events that led to the MDA of 1976 and is repeatedly cited in the legislative history. *Id.* at 8 (noting that there were over 500 lawsuits seeking damages at the time of the Report); S. Rep. 94-33, at 1 (1975) ("Senate Report") (submitted by Senator Kennedy). In light of the Dalkon Shield tragedy and other information received in hearings on the bill, the focus of the legislation was protecting consumers from unsafe products.

The MDA was designed "to provide for the safety and effectiveness of medical devices intended for human use, and for other purposes." Pub. L. No. 94-295, 90 Stat. 539 (1976); *see also* House Report at 12 (MDA intended "to assure that the public is protected from unsafe and ineffective medical devices, that health professionals have more confidence in the devices they use or prescribe, and that innovations in medical device technology are not stifled by unnecessary re-

strictions."). Throughout the legislative history of the Act are expressions of concern about "faulty devices" and their toll on Americans. *E.g.*, Hearing on H.R. 5545 Before the House Subcommittee on Health and the Environment of the Committee on Interstate and Foreign Commerce, 94th Cong. 1 (1975) (statement of Rep. Paul Rogers, Chairman of the House Subcommittee on Health and the Environment). As one of the *amici* declared on the floor of the Senate during debate on the bill: "The legislation is written so that the benefit of the doubt is always given to the consumer." 121 Cong. Rec. S6140 (Apr. 17, 1975) (Statement of Sen. Kennedy). Thus, recognizing that many of the harms caused by medical devices were preventable, Congress enacted the MDA.

Under the MDA, the term "device" includes a vast array of products, including tongue depressors, band-aids, tampons, bone screws, hip replacements, artificial heart valves, and pacemakers. *See* 21 U.S.C. § 321(h). Each medical device falls into one of three classes. Class I devices, for example tongue depressors, are those for which the MDA's "general controls" applicable to all devices, such as record-keeping and good manufacturing guidelines, are sufficient to provide reasonable assurance of safety and effectiveness. *See* 21 U.S.C. §§ 360i(a), 360j(f). Class II devices, for example tampons, are those for which special controls are necessary to protect the public health. Special controls include performance standards, special labeling requirements, and post-market surveillance. 21 U.S.C. § 360c(a)(1)(B); 21 C.F.R. § 874.3300(b)(2).

Finally, Class III devices operate to sustain human life, are important in preventing impairment of human health, or pose potentially unreasonable risks to patients. 21 U.S.C. § 360c(a)(1)(C); *see* 21 C.F.R. § 860.3(c)(3). Class III devices must undergo pre-market approval by the FDA, *see* 21 U.S.C. §§ 360e(b)(1); 360e(c)(1), unless the device qualifies for one of the statute's exceptions. The balloon catheter in-

volved in this case is an example of a Class III device that underwent pre-market approval.

**C. The MDA's Preemption Provision.**

When it considered the MDA, Congress was aware of various state programs requiring pre-market approval of medical devices, and the House Report specifically noted that in 1970 California had adopted the Sherman Food, Drug, and Cosmetic Law, which the Committee described as "comprehensive" in its regulation of medical devices. House Report at 45. Although it adopted a comprehensive federal regulatory system, Congress gave FDA the authority to preserve more stringent state provisions where they existed, finding them to be "a useful supplement to Federal regulation." *Id.*

In 21 U.S.C. § 360k(a), the MDA provided that States may not "establish or continue in effect with respect to a device . . . any requirement" that is "different from, or in addition to" certain federal device "requirement[s]" imposed under the MDA. 21 U.S.C. § 360k(a). However, Congress authorized FDA to grant state and local governments exemptions from preemption for their medical device laws in certain circumstances, including when the requirement is more stringent than the federal requirement. *See* 21 U.S.C. § 360k(b); House Report at 4. Congress noted that the more stringent program established by the state of California was an example of a program that should be allowed to continue to operate even after passage of federal legislation. House Report at 46. Since passage of the MDA, FDA has granted several such exemptions to States that have passed more stringent regulations regarding hearing aids. *See, e.g.*, 21 C.F.R. §§ 808.53; 808.55; 808.69. Thus, consistent with the focus on public safety in the MDA, Congress favored patient protection over nationwide uniformity.

**D. The *Lohr* Decision.**

In 1996, this Court considered the scope of preemption in section 360k(a) in *Medtronic, Inc. v. Lohr*, 518 U.S. 470

(1996). In *Lohr*, the Court held that a state product liability lawsuit was not preempted with respect to a medical device that had *not* undergone pre-market approval. Nevertheless, some members of the Court discussed the issue of whether section 360k(a) preempts *any* tort suits.

In the plurality opinion by Justice Stevens, four members of this Court found no preemption in the *Lohr* case, but left open the issue of whether there could ever be preemption. Four members of the Court joined an opinion by Justice O'Connor that concluded that section 360k(a) did preempt product liability cases and that the product liability lawsuit in *Lohr* was preempted. Justice O'Connor relied heavily on the Court's interpretation of the Public Health Cigarette Smoking Act of 1969's preemption provision that the Court construed in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). Justice Breyer, in a separate opinion, agreed with Justice Stevens that there was no preemption in the *Lohr* case, but he also stated that "[o]ne can reasonably read the word 'requirement' as including the legal requirements that grow out of the application, in particular circumstances, of a State's tort law." *Lohr*, 518 U.S. at 504.[3]

That "requirement" in the Public Health Cigarette Smoking Act of 1969, Pub. L. No. 91-222, 84 Stat. 87 (codified at 15 U.S.C. § 1331, *et seq.*) ("PHCSA"), as amended and codified, 15 U.S.C. §§ 1331-40, may include common law tort

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[3] In his opinion, Justice Breyer discussed the tension between an FDA regulation that hearing aids be designed with a two-inch wire and a product liability lawsuit alleging the manufacturer should have used a safer, one-inch wire. As explained below, in enacting the express preemption provision contained in section 360k(a), Congress did not intend to preempt state product liability actions. Nevertheless, conflicts between state and federal law may be addressed under principles of implied conflict preemption. In this brief, *amici* do not address the complex issue of whether a state court verdict might be subject to implied conflict preemption, which was neither raised in nor decided by the court of appeals.

claims does not mandate a conclusion that use of the same term in a very different statute with different goals means the same thing. *Amici* explain below that use of the term "requirement" in the MDA, the structure of the MDA, the motivation of Congress in enacting the MDA, and other legislative history demonstrate that the term "requirement" in the MDA does not encompass state tort action. As Professor Walter Wheeler Cook cautioned some 75 years ago, although the tendency to assume that the same word means the same thing in different contexts "has all the tenacity of original sin," it "must constantly be guarded against." Walter W. Cook, *"Substance" and "Procedure" in the Conflict of Laws*, 42 Yale L.J. 333, 337 (1933).

## SUMMARY OF ARGUMENT

The language of section 360k and its legislative history demonstrate that Congress did not intend to preempt state tort suits. The legislative history demonstrates that Congress included section 360k in the MDA for one specific reason--to reconcile the new federal regulatory scheme with device regulatory schemes that states had adopted in the absence of federal regulation. There is no suggestion anywhere in the legislative history to suggest that Congress even considered preempting state tort suits, much less that it intended to preempt such suits.

Congress amended the FFDCA numerous times between 1938, when it enacted the FFDCA, and 1976, when it enacted the MDA, to increase the authority of the FDA, yet it never included a provision expressly preempting state positive law or state tort suits. Because there were no parallel state regulatory schemes, Congress had no occasion to preempt state positive law. A preemption provision would have been necessary had Congress been concerned about state tort actions against the manufacturers that it was regulating. It was not.

Section 360k(a) prohibits States from establishing a "requirement" that is different from a federal "requirement" ap-

plicable to a medical device. Thus, in order to trigger preemption, there must be both a federal and a state requirement. Federal requirements are established by the statute, agency regulations, and in some cases by an order applicable to a specific product. For example, FDA is authorized to promulgate performance standards applicable to medical devices. These standards may establish specific requirements for a device. A state regulation that imposed a different requirement would be preempted by section 360k(a). However, the structure of the MDA makes clear that the use of the word "requirement" in the context of federal action does not extend to a lawsuit. The logical and most plausible inference is that the reference to a state "requirement" in the same subsection of the MDA does not encompass state lawsuits.

Any doubt about the meaning of section 360k(a) is resolved by section 360k(b), which permits states to obtain an exemption from section 360k(a) for a state "requirement." Once again, the structure of the MDA reveals that Congress could not have intended "requirement" to encompass a lawsuit: there is no practical way for a state to seek an exemption for a lawsuit, either before or after a jury verdict. Since "requirement" in subsection (b) does not include tort lawsuits, the term "requirement" in subsection (a) also does not include such lawsuits.

## ARGUMENT

### THE LANGUAGE OF THE MDA AND ITS LEGISLATIVE HISTORY DEMONSTRATE THAT CONGRESS DID NOT INTEND TO PREEMPT STATE COMMON LAW TORT SUITS.

This Court repeatedly has stated that the touchstone for express preemption is the intent of Congress. *English v. General Electric Co.*, 496 U.S. 72, 78-79 (1990); *Shaw v. Delta Air Lines, Inc.*, 463 U.S. 85, 95 (1983). The relevant intent must be discerned from the language of the statute, its structure, purpose, and subject matter. *Cipollone*, 505 U.S. at

545 (Scalia, J., concurring in the judgment in part and dissenting in part). In addition, there is a presumption against Congress's displacing state law, especially in an area of traditional state authority, such as tort law. *See id.* at 516; *see also Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005).

Since 1938, when Congress adopted the FFDCA, which required pre-market approval of "new drugs," it has amended the Act numerous times, in 1958 to require pre-market approval of food additives, in 1960 to require pre-market approval of color additives, in 1962 to require that human drugs be proven to be effective in the pre-market approval process, and in 1968 to require pre-market approval of new animal drugs.[4]

At the time that it adopted each of these provisions, insofar as *amici* are aware, there were no competing state regulatory schemes covering any of these product categories, and in each case Congress did not include a preemption provision in any of these laws. Insofar as *amici* are aware, there was no interest in Congress in preempting state product liability lawsuits, although such suits, especially involving pharmaceuticals, were an ever-present backdrop. *See, e.g.*, Paul D. Rheingold, *The MER/29 Story – An Instance of Successful Mass Disaster Litigation*, 56 Cal. L. Rev. 116 (1968) (describing MER/29 litigation, the first drug-related mass tort case, which was emerging as Congress was considering the 1962 Amendments).

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[4] Food Additives Amendment of 1958, Pub. L. No. 85-829, 72 Stat. 1785 (1958) (codified as amended at 21 U.S.C. § 348); Color Additive Amendments of 1960, Pub. L. No. 86-618, 74 Stat. 399 (1960) (codified as amended at 21 U.S.C. § 376); Drug Amendments of 1962, Pub. L. No. 87-781, 76 Stat. 780 (1962) (codified as amended at 21 U.S.C. § 321, *et seq.*); Animal Drug Amendments of 1968, Pub. L. No. 90-399, 82 Stat. 343 (1968) (codified as amended at 21 U.S.C. § 382).

As noted above, in 1976, when Congress enacted the MDA, the state of California had adopted a comprehensive regulatory system applicable to medical devices. This led Congress to include for the first time in the FFDCA a provision providing for preemption of certain state device regulatory requirements. The provision, section 521(a) of the FFDCA, added by the MDA, provides as follows:

> Except as provided in subsection (b), no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any *requirement* –
>
> (1) which is different from, or in addition to, any *requirement* applicable under this Act to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a *requirement applicable to the device under this Act.*

21 U.S.C. § 360k(a) (emphasis supplied).

The purpose of section 360k(a) is clear on its face. First, preemption applies only when there is a "requirement applicable to the device under this Act." 21 U.S.C. § 360k(a)(1). For example, under section 360d, FDA may issue performance standards, which are mandatory requirements applicable to specific devices. *See, e.g.*, 21 C.F.R. § 801.410 (providing specific requirements for impact-resistant lenses in eyeglasses and sunglasses). Thus, if FDA mandates that eyeglass lenses must pass a specific test prior to being labeled as impact-resistant, then section 360k(a) would bar a state from adopting a standard that is "different from, or in addition to" the FDA requirement.

Similarly, under section 360j(e), FDA, by regulation, may restrict the sale, distribution or use of devices. For example, FDA can mandate that a device be used only by physicians with specific training relevant to a product's use.

Such a regulation also could preempt a state requirement applicable to the same device that addressed the same subject matter as the regulation. The statute gives FDA other authority to impose requirements. *See, e.g.*, 21 U.S.C. § 360i (authorizing FDA to require records and reports). Every requirement imposed on a medical device manufacturer by FDA is imposed by the statute, by regulation or by an order applicable to a specific device.[5] None is issued by a court or any other body. In other words, "requirement," the second and third time it is used in section 360k(a), means a requirement imposed by federal positive law.

Section 360k(a) applies to a state "requirement" that is "different from or in addition to" the federal "requirement." Just as the federal "requirement" must be a regulation or specific agency pronouncement under the Act, Congress intended for the term state "requirement" to apply to medical device requirements enacted by a legislature or promulgated by an administrative agency. The straightforward meaning of section 360k(a) is that the provision was intended to preempt state laws and regulations applicable to specific devices that are "different from, or in addition to" any federal "requirement."

The preemption of state requirements is not absolute. Congress provided that states could apply for an exemption as to statutes and regulations preempted by subsection (a). Thus, in subsection (b), it provided the states an opportunity to obtain an exemption to the general preemption rule. Section 360k(b) states:

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[5] For example, under section 360e(d)(1)(B)(ii), in its approval decision, FDA may by order impose the same restriction that it may impose under section 360j(e) by regulation for all devices (for example, mandating that a device be used only by physicians with specific training relevant to the product's use). Such an order would be a requirement under section 360k(a).

> (b) Upon application of a State or a political subdivision thereof, the Secretary may, by regulation promulgated after notice and opportunity for an oral hearing, exempt from subsection (a), under such conditions as may be prescribed in such regulation, a *requirement* of such State or political subdivision applicable to a device intended for human use if –
>
> (1) the *requirement* is more stringent than a *requirement* under this Act which would be applicable to the device if an exemption were not in effect under this subsection; or
>
> (2) the *requirement* –
>
> (A) is required by compelling local conditions, and
>
> (B) compliance with the *requirement* would not cause the device to be in violation of any applicable *requirement* under this Act.

21 U.S.C. § 360k(b) (emphasis supplied).

As discussed above, when Congress enacted section 360k(b), it was aware that California already had adopted a regulatory scheme for medical devices.[6] Accordingly, in section 360k(b)(i), Congress provided that a state could apply to FDA for an exemption from section 360k(a) if the state requirement is more stringent than the federal requirement. Section 360k(b)(2) permits exemption from section 360k(a) because of compelling local conditions. These exemptions plainly contemplated that states that had laws or regulations "different from or in addition to" FDA *requirements* could obtain an exemption from FDA. It is difficult to imagine

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[6] *See* 1970 Cal. Stat. 3270 (requiring new medical devices receive pre-marketing approval before they can be sold).

how such an exemption could apply to a products liability jury verdict, either in advance of or after such a verdict.

Yet, if section 360k(a) is read to preempt certain product liability claims, then section 360k(b) must be read to provide an opportunity for an exemption from such claims, since both provisions apply only to federal and state "requirements." As this Court explained in *Commissioner v. Lundy*, 516 U.S. 235, 249-50 (1996), there is "no reason to believe that Congress meant the term . . . to mean one thing" in the first part of section 360k(a) "but to mean something else altogether" the next two times it appears.[7] As the Court further explained, "the interrelationship and close proximity of these provisions . . . 'present[] a classic case for application of the normal rule of statutory construction that identical words used in different parts of the same act are intended to have the same meaning.'" *Id.* at 250 (quoting *Sullivan v. Stroop*, 496 U.S. 478, 484 (1990) (internal quotations and case citations omitted)); *see also, e.g., United States Department of Treasury v. Fabe*, 508 U.S. 491, 515 (1993) (Kennedy, J., dissenting) (referring to foregoing principle as a "basic rule of statutory construction"). Thus, since "requirement" in section 360k(b) must be limited to state statutes and regulations,

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[7] *Amici* urge here that the word "requirement" when it appears multiple times in the same section of a statute should be understood to mean the same thing. By contrast, *amici* have argued that the use of the word "requirement" in a different statute, the PHCSA, should not be understood to mean the same thing as it does in the MDA. The PHCSA was enacted by a different Congress at a different time and had different purposes than the MDA, including an explicit purpose of avoiding inconsistent state requirements for the labeling on cigarette packaging and in advertising and promoting cigarettes, 15 U.S.C. § 1331. The PHCSA contained specific requirements for the language to be used on cigarette packages and in advertising and promotion, and did not contain other usages of "requirement" in the statutory language inconsistent with a meaning that includes state common law. Thus, the two contentions by *amici* about the appropriate interpretation of "requirement" are not inconsistent.

that same term in section 360k(a) must be limited in the same way. If Congress had meant there to be different meanings for the same word employed in the same subsection, one would have expected it to say so. *Gustafson v. Alloyd Co., Inc.*, 513 U.S. 561, 573 (1995). Congress's silence on this matter speaks loudly about its intent. There is no room in the plain language of the statute for an interpretation that that term could also include "requirements" imposed by product liability tort suits.

There also is no indication in the Congressional hearings, the Committee Reports or the debates on the House or Senate floor that even a single member of the House or Senate believed that section 360k would bar state common law remedies against manufacturers. Of course, the existence of such remedies was at the forefront of the consideration of the MDA, since prior to adopting the amendments, Congress had heard extensive testimony about the Dalkon Shield tragedy.[8] There is no indication in the Congressional history of the MDA that Congress intended to prevent state tort actions, which is strong evidence that such preemption was not intended.[9] As Justice Stevens observed in *Lohr*, the absence of any hint of preempting common law claims in the entirety of the MDA legislative history is "spectacularly odd" if such preemption was intended by Congress. *Lohr*, 518 U.S. at 491; *see also Bates*, 544 U.S. at 449 (2005) ("The long his-

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[8] The MDA was enacted against a backdrop of a long history of tort suits involving medical devices. *See* Edward M. Swartz, *Products Liability: Manufacturer's Responsibility for Defective or Negligently Designed Medical and Surgical Instruments*, 18 DePaul L. Rev. 348, 358 (1969); R.D. Hursh, *Annotation, Liability of Manufacturer or Seller For Injury Caused By Medical and Health Supplies, Appliances, and Equipment*, 79 A.L.R.2d 401 (1961).

[9] "A careful perusal of the entire legislative history reveals no mention of preempting state common law tort claims." Robert S. Adler & Richard A. Mann, *Preemption and Medical Devices: The Courts Run Amok*, 59 Mo. L. Rev. 895, 923-24 n.128 (1994).

tory of tort litigation against manufacturers . . . adds force to the basic presumption against pre-emption. If Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly."); *Chisom v. Roemer*, 501 U.S. 380, 396 (1991) ("if Congress had such an intent, Congress would have made it explicit in the statute, or at least some of the Members would have identified or mentioned it at some point in the unusually extensive legislative history.").

It is, thus, not surprising that public commentary following the enactment of the MDA also does not even suggest the *possibility* that the Medical Device Amendments could preempt state common law product liability actions. *See Lohr*, 518 U.S. at 491 n.13 (plurality opinion). Similarly, in 1977, when it proposed 21 C.F.R. § 808.1(b) to implement the MDA, FDA directed applicants for an exemption to inform it as to "whether the statute, rule, or regulation has been subject to judicial or administrative interpretations that give it legal meanings in the State or political subdivision that are not readily apparent from the face of the document"). 42 Fed. Reg. 30383, 30385 (June 14, 1977); *accord* 43 Fed. Reg. 18661, 18663 (May 2, 1978). It is also relevant that the FDA's regulations declare that a state "requirement" is not "eligible for exemption from preemption" unless it has been "issued in final form." 21 C.F.R. § 808.5(b)(2). Regulations, ordinances and similar enactments are "issued" in "final form." Product liability judgments are not "issued," and, although they do become final, they are not refined into a "final form." FDA understood that the preemption provision applied to a "statute, rule, or regulation," and not to product liability lawsuits.

Indeed, the first reported decision that *amici* can locate in which preemption under section 360k(a) was employed as a defense to a state tort suit is *Ignace v. International Playtex*,

*Inc.*, No. 86-C-480-C, 1987 WL 93996 (W.D. Wis. Aug. 14, 1987).[10] Thus, it did not occur to attorneys in the medical device industry and the nation's product liability attorneys, who are paid to identify defenses to litigation against their clients, that Congress intended in section 360k(a) to preempt common law tort claims until more than a decade after the statute was enacted. That they began to assert preemption is likely the result of the emergence, in the mid-1980s, of cases claiming preemption based on the Federal Cigarette Labeling and Advertising Act. *See, e.g., Palmer v. Liggett Group, Inc.*, 633 F. Supp. 1171 (D. Mass. 1986); *Roysdon v. R.J. Reynolds Tobacco Co.*, 623 F. Supp. 1189 (E.D. Tenn.1985).

It was not until the decision in *Cipollone* in 1992 that Congress was aware that this Court might interpret the term "requirement" in a statutory preemption provision to include state product liability lawsuits. At this point, Congress began explicitly stating in statutes that the term "requirement" in preemption provisions did not preempt product liability actions. In two amendments to the FFDCA since 1992, in which Congress preempted state "requirements," Congress explicitly stated that product liability cases were not preempted. Thus, in § 751 of the FFDCA, 21 U.S.C. § 379r, which preempted certain "requirement[s]" applicable to nonprescription drugs, Congress added subsection (e) titled "No effect on product liability law." Subsection (e) states that "[n]othing in this section shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." If Congress had had any indication in 1976 when it enacted the MDA that a court

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[10] There is also a slightly earlier, unreported case: *Muzatko v. International Playtex, Inc.*, No. 85-C-1540, 1987 U.S. Dist. LEXIS 14281 (E.D. Wis. May 14, 1987), cited in *Edmondson v. International Playtex, Inc.*, 678 F. Supp. 1571 (N.D. Ga. 1987). Notably, in all of these cases, FDA had promulgated a regulation mandating certain information about tampon risks to be placed on the product's labeling. *See* 21 C.F.R. § 801.430.

would interpret the term "requirement" in section 360k to include state product liability law, then it would have included such a provision in the MDA.[11]

Permitting state design defect claims also is consistent with the Congressional purpose in enacting the MDA. Denying them is not. As noted previously, in the aftermath of the Dalkon Shield tragedy, Congress's primary focus was ensuring the safety of medical devices when it enacted the MDA. Modern design defect litigation frequently requires a plaintiff to identify an alternative design that would make the product safer. *See* Restatement (Third) of Torts: Products Liability § 2(b) (1998) (product has defective design when a "reasonable alternative design" would reduce the foreseeable risks of the product). Moreover, if design defect litigation for PMA devices is preempted, the incentive created by tort litigation to identify better designs in the wake of adverse events suffered by users of those devices will be lost. *See Bates*, 544 U.S. at 451 ("the specter of damage actions may provide manufacturers with added dynamic incentives to continue to keep abreast of all possible injuries stemming from use of their product so as to forestall such actions through product improvement") (citation omitted). Congress might have decided that preemption is appropriate if the FDA were deciding the optimal design of medical devices in the PMA process, but that is not the case.

With respect to devices subject to pre-market approval, the basic determination that the FDA makes is whether the device--designed in whatever fashion the manufacturer has determined--is safe and effective for use. *See* Brief of the United States as Amicus Curiae at 20-21, *Lohr v. Medtronics*,

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[11] In 1997, Congress also amended the FFDCA to include a provision preempting state and local requirements for the labeling or packaging of cosmetics, which is codified at 21 U.S.C. § 379s(a). Congress also included a savings clause for state product liability claims in section 379s(d).

*Inc.*, *supra*. If the device meets this statutory standard, FDA has no authority to deny approval even if an alternative design might make the device safer than the design proposed by the applicant. In other words, the manufacturer – not the FDA – has control over the design of the device.

Moreover, clinical trials of medical devices will not identify all of the significant risks involved in the use of the device. Risks that are relatively rare but important will emerge only when a device is released into a larger and more heterogeneous population. *See* Institute of Medicine, *Safe Medical Devices for Children* 113 (2005) (explaining the importance of adverse event reporting and monitoring of medical devices to identify "serious problems" with devices in light of its post-approval use "with many more patients, with different patient populations (*e.g.*, children), in different ways (*e.g.*, involving ad hoc modifications for pediatric use), for different purposes, in new and possibly less well-equipped settings, over longer periods, and, sometimes, by less experienced or skilled clinicians and care teams"); *see also* General Accounting Office, *FDA Drug Review: Postapproval Risks 1976-85* at 52 (1990) (finding that over 50 percent of prescription drugs approved by the FDA had serious risks that went undetected during pre-marketing clinical testing); Institute of Medicine, *The Future of Drug Safety: Promoting and Protecting the Health of the Public* (2007) (explaining the difficulty of determining all drug risks during pre-market testing).

After a device has been approved, new information about design changes to the device that may improve safety or efficacy is largely in the control of the manufacturer. Moreover, the FDA has limited authority to force a manufacturer to make a design change even if it is aware that the change would improve the device. The FDA can initiate proceedings to withdraw the product from the market, but the agency must establish that the product no longer meets the statute's safety and efficacy requirements and, in any event, this can

be a time consuming process.[12] In this context, design defect litigation affords an opportunity to identify those newly emergent risks and to consider alternatives to the design that would further consumer safety–the focus of the MDA. *See* Mary Lyndon, *Tort Law and Technology*, 12 Yale J. on Reg. 137, 176 (1995) ("[T]ort law's signals contain necessary basic messages that are not delivered through any other medium . . . offer[ing] advantages that we need to account for before preempting tort law.").

The Chief Counsel of the FDA, in the wake of *Lohr*, trenchantly explained this concern:

> FDA regulation of a device cannot anticipate and protect against all safety risks to individual consumers. Even the most thorough regulation of a product such as a critical medical device may fail to identify potential problems presented by the product. Regulation cannot protect against all possible injuries that might result from use of a device over time. Preemption of all such claims would result in the loss of a significant layer of consumer protection, leaving consumers without a remedy for injuries caused by defective medical devices. Moreover, FDA's regulation of devices would have been accorded an entirely different weight in private tort litigation than its counterpart regulation of drugs and biologics. This disparity is neither justified nor appropriate, nor does the agency believe it was intended by Congress when section 521 was enacted.

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[12] *See, e.g.*, 21 U.S.C. § 360e(e)(1) (requiring notice, an opportunity for an informal hearing, and, where appropriate, convening an advisory committee) & 21 U.S.C. § 360e(e)(2) (providing for review of an order withdrawing approval).

Margaret J. Porter, *The* Lohr *Decision: FDA Perspective and Position*, 52 Food & Drug L.J. 7, 11 (1997); *see also* David A. Vladeck, *Preemption and Regulatory Failure*, 33 Pepp. L Rev.95, 97 (2005) ("Since the founding of our Republic, tort liability has filled [regulatory gaps].").

## CONCLUSION

Congress was fully aware of widespread tort law suits over medical devices, yet there is nothing in the legislative history to suggest an intent preempt such suits. At the time the MDA was enacted, Congress did not understand the term "requirement" to include state tort law verdicts. More recent FDA legislation has clarified that preemption of state requirements does not include tort lawsuits. If Congress had intended to preempt state tort law suits, it would have explicitly done so. Taking into account the plain language of the MDA preemption provision, the absence of any indication in the legislative history that Congress even considered the possibility that the provision would preempt state tort suits, the presumption against preemption, and the legislative purpose of the MDA, it is plain that the "requirements" preempted under the statute do not include state tort law suits.

Based upon the foregoing, the *amici* respectfully request that this Court reverse the decision of the Second Circuit and remand the case for trial.

Respectfully submitted,

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SUPREME COURT, U.S.

IN THE

# Supreme Court of the United States

CHARLES R. RIEGEL, *et ux.*,

*Petitioners*,

*v.*

MEDTRONIC, INC.,

*Respondent.*

ON WRIT OF CERTIORARI TO THE
UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

**BRIEF FOR THE STATES OF NEW YORK, ARIZONA, ARKANSAS, CONNECTICUT, DELAWARE, FLORIDA, HAWAII, IDAHO, ILLINOIS, IOWA, KANSAS, MARYLAND, MASSACHUSETTS, MINNESOTA, MISSISSIPPI, MISSOURI, MONTANA, NEVADA, NEW MEXICO, NORTH DAKOTA, OHIO, OREGON, SOUTH CAROLINA, TENNESSEE, UTAH, VERMONT, WASHINGTON, WEST VIRGINIA, WISCONSIN, AND WYOMING, AND THE DISTRICT OF COLUMBIA AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS**


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## QUESTION PRESENTED

Whether the express preemption provision of the Medical Device Amendments to the Food, Drug, and Cosmetic Act, 21 U.S.C. § 360k(a), preempts state-law claims seeking damages for injuries caused by medical devices that received premarket approval from the Food and Drug Administration.

## TABLE OF CONTENTS

*Page*

QUESTION PRESENTED ..... i

TABLE OF CONTENTS ..... ii

TABLE OF CITED AUTHORITIES ..... iv

INTEREST OF THE AMICI ..... 1

ARGUMENT ..... 2

I. The Text of the MDA and Implementing Regulations Demonstrate that Congress Intended to Allow Room for State Law to Operate Where It Furthers the Act's Fundamental Safety Objectives. ..... 2

A. The Limited Scope of Section 360k, and the Section's Exemption Mechanism, Show that Congress Viewed Federal Device Regulation and Continued Application of State Law as Largely Compatible. ..... 6

B. The MDA's Saving Clause Shows that Congress Took Care to Preserve Manufacturers' Liability For Damages Under State Law Where Approved Devices Prove Unsafe and Cause Injury. ..... 11

II. The MDA Does Not Evince a Clear and Manifest Congressional Purpose that the Federal Premarket Approval Process Should Replace Postmarket State Product Liability Suits. ..... 12

## *Contents*

*Page*

III. The FDA's Newly Minted Position on the Preemptive Effect of Premarket Approval Is Entitled to No Weight. ..... 22

CONCLUSION ..... 26

## TABLE OF CITED AUTHORITIES

*Page*

**Cases**

*Bates v. Dow Agrosciences L.L.C.*,
544 U.S. 431 (2005) ..... *passim*

*Blunt v. Medtronic, Inc.*,
2007 Wisc. App. LEXIS 667
(Wis. App. July 31, 2007) ..... 15

*Chevron U.S.A., Inc. v.*
*Natural Resources Defense Council, Inc.*,
467 U.S. 837 (1984) ..... 22

*Denny v. Ford Motor Co.*,
87 N.Y.2d 248 (1995) ..... 8

*Desiano v. Warner-Lambert & Co.*,
467 F.3d 85 (2d Cir. 2006) ..... 23

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346 U.S. 100 (1953) ..... 1

*Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg.*
*& Constr. Trades Council*,
485 U.S. 568 (1988) ..... 24

*Geier v. Am. Honda Motor Co.*,
529 U.S. 861 (2000) ..... 23, 24

*Hillsborough County v. Automated Med. Labs., Inc.*,
471 U.S. 707 (1985) ..... 2

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217 N.Y. 382 (1916) ..... 3

*Cited Authorities*

*Page*

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464 U.S. 238 (1984) ..... 5, 12

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517 U.S. 735 (1996) ..... 22

*Solid Waste Agency of N. Cook County v. U.S. Army Corps of Engineers*,
531 U.S. 159 (2001) ..... 24

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537 U.S. 51 (2002) ..... 4

*Watters v. Wachovia Bank, N.A.*,
127 S. Ct. 1559 (2007) ..... 22

**Federal Statutes and Regulations**

21 U.S.C. § 360c ..... 12

21 U.S.C. § 360e ..... 15

21 U.S.C. § 360h ..... 11, 19

21 U.S.C. § 360i ..... 19

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21 C.F.R. § 808.1 ..... 7, 8, 23, 25

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*Page*

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Safe Medical Devices Act of 1990, Pub. L. 101-629, 104 Stat. 4511 ..... 19

**State Statutes**

New York Executive Law § 63(12) ..... 7

**Other Authorities**

122 Cong. Rec. 5,859 (1976) ..... 9

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## INTEREST OF THE AMICI

In our federal system, the amici States have historically taken the leading role in matters of health and safety.[1] In that arena, state product liability law has long served to provide incentives for product manufacturers to make their products safe and effective, to compensate individual consumers injured by unsafe products, and to spread the risks of product defects across large segments of society by requiring firms to internalize damages from injuries or deaths caused by their products as costs of doing business.

By enacting the Medical Device Amendments ("MDA") in 1976, Congress for the first time vested the Food and Drug Administration ("FDA") with new and broad authority to regulate medical devices intended for human use. This included the responsibility of pre-clearing the newest and highest-risk medical devices before they were permitted to be brought to market. This premarket approval ("PMA") process entailing *ex ante* review of proposed new medical devices no doubt prevents many unsafe devices from ever being sold, but it is no substitute for *ex post* adjudication in product liability suits based on individuals' actual experiences with a device under real-world conditions. The PMA process and state tort law thus work together to help ensure the safety of medical devices.

The lower court's holding that the PMA process broadly displaces state product liability suits involving approved devices, if not reversed by this Court, would imperil the health and safety of amici States' consumers. It would also

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1. Amicus the District of Columbia is not a State. However, Congress has delegated broad police powers to the District to enable it to protect the health and safety of its residents. *See, e.g., District of Columbia v. John R. Thompson Co.*, 346 U.S. 100, 109 (1953). The District of Columbia, therefore, also has a strong interest in the preemption issue before the Court.

unnecessarily and improvidently nullify state law where it complements, and does not conflict with, the goals of the federal statute.

## ARGUMENT

### I. The Text of the MDA and Implementing Regulations Demonstrate that Congress Intended to Allow Room for State Law to Operate Where It Furthers the Act's Fundamental Safety Objectives.

As this Court held in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), analysis of the scope of the MDA's preemption clause, 21 U.S.C. § 360k(a), is guided by two overarching principles. First, the purpose of Congress is the "ultimate touch-stone" in all preemption cases, requiring consideration of the statutory text and structure, as well as "the reviewing court's reasoned understanding of the way in which Congress intended the statute and its surrounding regulatory scheme to affect business, consumers, and the law." *Lohr*, 518 U.S. at 485-86. Second, respect for the States' role as "independent sovereigns in our federal system" gives rise to a presumption against preemption in fields that the states have historically occupied. *Id.* at 485. In those areas, the congressional purpose to preempt must be "clear and manifest" for the States' traditional powers to be found superseded. *Bates v. Dow Agrosciences L.L.C.*, 544 U.S. 431, 449 (2005). Health and safety are just such fields of traditional state power, *see Hillsborough County v. Automated Med. Labs., Inc.*, 471 U.S. 707, 715 (1985), and were Congress's motivating concerns in enacting the MDA.

The MDA was enacted in 1976 to enhance the safety and effectiveness of medical devices by providing increased statutory authority for the FDA to regulate them. *See, e.g.*, S. Rep. 94-33, at 1-2 (1976), *reprinted in* 1976 U.S.C.C.A.N.

1070, 1070-71.[2] The Act was passed against the backdrop of numerous reported deaths and serious injuries caused by newly developed medical devices, such as the Dalkon Shield intrauterine device, pacemakers, and artificial heart valves. S. Rep. 94-33, at 1-2, 6-7, *reprinted in* 1976 U.S.C.C.A.N. at 1070-1071, 1076. It was also enacted in the context of a long history of tort litigation under state law to protect individual consumers from dangerous and defective products. *See, e.g., MacPherson v. Buick Motor Co.*, 217 N.Y. 382 (1916) (Cardozo, J.) (developing theory of strict product liability); *cf. Lohr*, 518 U.S. at 485 (acknowledging "the historic primacy of state regulation of matters of health and safety"). That history "adds force to the basic presumption against pre-emption." *Bates*, 544 U.S. at 449.

In this case, the issue is whether the FDA's grant of premarket approval to a new medical device preempts product liability claims under state law. As explained in detail below, neither the text nor the legislative history of the MDA indicates that Congress intended the PMA process to have such broad preemptive effect. The MDA is a safety statute, not a tort reform statute, and the Act makes clear that there is ample room for state law to serve a complementary role in ensuring the safety of medical devices.

---

2. Although some comments in the legislative history reflect a subsidiary concern about hampering medical innovation, those comments "were related more to the risk of *additional* federal and state regulation rather than the danger of pre-existing duties under common law." *Lohr*, 518 U.S. at 490 (plurality opinion). As *Lohr* noted, the legislative history contains no references to fears about the impact of state "product liability actions" on "the development of medical devices." *Id.* Any congressional intention to avoid overregulation "was manifested primarily through fewer substantive requirements under the Act, not the pre-emption provision." *Id.* "[F]urthermore, any such concern was far outweighed by concerns about the primary issue motivating the MDA's enactment: the safety of those who use medical devices." *Id.* at 490-91.

The MDA contains several distinct provisions that demonstrate the complementary roles of state and federal regulation in this area. First, the express-preemption clause in § 360k(a) is narrowly drawn, displacing state medical-device regulation only where it conflicts with a particular federal interest, as embodied in a specific federal counterpart regulation. Second, in § 360k(b), Congress authorized the FDA to grant an exemption from preemption to state laws in defined circumstances — including where state law is more stringent, and thus more protective of patients and consumers, than federal regulation. Third, the Act includes a saving clause, § 360h(d), which expressly provides that although federal remedies may sometimes provide a limited benefit to individual patients or consumers where devices prove defective, those remedies are not meant to relieve a manufacturer from existing liability for damages under state law.

Where the FDA grants a PMA to permit a new medical device to be brought to market, state tort suits maintain an important place in monitoring the safety of the device after it is marketed, based on the device's actual use under real-world conditions. Indeed, this Court has repeatedly recognized that state common-law claims can play an important, complementary role in furthering the goals of federal safety legislation. *See, e.g., Bates*, 544 U.S. at 451 (explaining that state tort suits can serve as a "catalyst" in exposing new hazards and bringing new information to attention of federal agencies); *Sprietsma v. Mercury Marine*, 537 U.S. 51, 64 (2002) ("It would have been perfectly rational for Congress not to pre-empt common-law claims, which — unlike most administrative and legislative regulations — necessarily perform an important remedial role in compensating accident victims.").

It is simply implausible that Congress, when it charged the FDA in 1976 to begin conducting *ex ante* review of new medical devices based on clinical data and other information

provided by the device manufacturer, would have meant to supersede all of state tort law in the area of device safety. Even more far-fetched is the notion that Congress would have displaced state common law so broadly without comment, and with no workable avenue for the FDA to grant exemptions from preemption when general common-law duties promote the underlying goal of ensuring device safety, as the agency can do when state medical-device statutes or regulations would otherwise be preempted.

Congress's silence as to whether common-law remedies are preempted by the PMA process "takes on added significance in light of Congress' failure to provide any federal remedy" for injuries, including deaths, caused by unsafe medical devices, the very danger that prompted the MDA's enactment. *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984); *see also Bates*, 544 U.S. at 449 (emphasizing that "[i]f Congress had intended to deprive injured parties of a long available form of compensation, it surely would have expressed that intent more clearly"). Like many other federal statutory schemes in the area of health and safety,[3] the MDA operates in conjunction with, and without preempting, state common-law remedies, which offer additional or parallel protection for consumers.

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3. *See, e.g., Bates*, 544 U.S. at 443-452 (Federal Insecticide, Fungicide and Rodenticide Act [FIFRA] does not preempt state common-law or statutory deceptive practices claims against pesticide and herbicide manufacturers); *Sprietsma*, 537 U.S. at 64-70 (Federal Boat Safety Act did not preempt common law tort claims against outboard motor manufacturer for failing to install a propeller guard).

### A. The Limited Scope of Section 360k, and the Section's Exemption Mechanism, Show that Congress Viewed Federal Device Regulation and Continued Application of State Law as Largely Compatible.

By its terms, the MDA's express-preemption clause, 21 U.S.C. § 360k(a), does not displace all state law that applies to medical devices or device manufacturers.[4] The clause is limited, and preempts only a state "requirement" established "with respect to" a medical device, and only when that requirement is "different from, or in addition to" a federal "requirement" "applicable to" the same device. The statutory language, together with the FDA regulations discussed below, "suggest that [the preemption clause's] focus is device-specific enactments of positive law by legislative or administrative bodies," not general common-law duties. *Lohr*, 518 U.S. at 489 (plurality opinion).

Moreover, pr[illegible]mption occurs only where there is a close correspondence in the subject matter and nature of the federal and state requirements. As this Court held in *Lohr*, § 360k(a) requires a carefully targeted "comparison between the allegedly pre-empting federal requirement and the allegedly pre-empted state requirement to determine whether they fall within the intended pre-emptive scope" of the statute. *Id.* at 500. The

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4. Section 360k(a) provides as follows:

> no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement–
>
> (1) which is different from, or in addition to, any requirement applicable under this Act [21 U.S.C. §§ 301 et seq.] to the device, and
>
> (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act. . . .

inquiry under § 360k(a) is both specific and narrow: preemption "occur[s] only where a particular state requirement threatens to interfere with a specific federal interest." *Id.*

That federal and state law are to a large extent complementary here, not at odds, is further shown by the FDA's preemption regulation, 21 C.F.R. § 808.1, which "substantially informed" this Court's analysis in *Lohr*. 518 U.S. at 495. The FDA played a significant role in the MDA's development, and the implementing regulations that the agency formally promulgated soon after the Act's passage provide critical insight about the intended scope of preemption. Like the statutory provisions discussed above, 21 C.F.R. § 808.1 demonstrates that much of state law was meant to be preserved.

Specifically, § 808.1(d) provides that state device requirements are preempted "only" when the FDA has established "specific counterpart regulations or . . . other specific requirements applicable to a particular device." And even where a device-specific federal requirement has been established, the regulation envisions that many kinds of state requirements will remain in force. For instance, there is no preemption of "State or local requirements of general applicability that relate only incidentally to medical devices." Exemptions From Federal Preemption of State and Local Device Requirements: Proposed Procedures for Consideration of Applications, 42 Fed. Reg. 30383, 30384 (June 14, 1977). In other words, a state requirement survives where its purpose "relates either to other products in addition to devices . . . or to unfair trade practices in which the requirements are not limited to devices." 21 C.F.R. § 808.1(d)(1).[5]

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5. This regulatory provision demonstrates that the FDA agrees that many state consumer-protection statutes are not preempted, such as New York Executive Law § 63(12), which permits the Attorney General of New York to investigate persistent fraud and illegality in the conduct of business within the State and to seek judicial redress where appropriate.

As specific examples of non-preempted general state requirements, the regulation identifies general electrical codes and the implied warranty of fitness under the Uniform Commercial Code ("U.C.C."). *Id.* The reference to U.C.C. implied warranties is most revealing, since that is a statutory source of product liability closely analogous to common-law negligence and strict liability, and indeed is frequently pleaded in conjunction with common-law theories. *See, e.g., Denny v. Ford Motor Co.*, 87 N.Y.2d 248, 255-56 (1995) (explaining historical development of U.C.C. warranty and strict liability claims and noting the "high degree of overlap" and essential congruence of both claims). Moreover, implied warranty claims, like common-law theories, require the application of a general liability standard to the facts and circumstances of a particular case. The regulatory statement that implied warranty claims survive therefore provides strong support for the conclusion that common-law claims should survive also.[6]

The FDA's preemption regulation also provides that § 360k(a) does not "preempt State or local requirements respecting general enforcement," such as inspection requirements for device-manufacturing facilities, or registration and licensing schemes for device manufacturers. *Id.* § 808.1(d)(6)(I). The regulation thus confirms that the MDA in large part embraces, not displaces, state law that touches on the safety and effectiveness of medical devices.

Further dispelling any notion that Congress viewed federal device regulation and the continued application of

6. The FDA's 1978 preemption regulation presumably singled out as not preempted statutes imposing general standards of care, like the U.C.C., but did not identify state common-law doctrines imposing similar general standards, because the regulation focused on § 360k(a)'s preemptive effect on state positive enactments, which were the statute's main target, not common-law duties.

state law as broadly incompatible, § 360k(b) of the MDA authorizes the FDA to exempt state requirements from preemption upon application by "a State or a political subdivision thereof," where either (1) the state requirement is "more stringent" than a counterpart federal requirement under the MDA, or (2) the state requirement is "required by compelling local conditions" and compliance would not cause the device to be in violation of any federal requirement.

The MDA's legislative history demonstrates that the exemption mechanism was no afterthought, but an integral element of Congress's design, reflecting its recognition that in "some situations . . . regulation of devices by States and localities would constitute a useful supplement to Federal regulation." H.R. Rep. No. 94-853, at 45 (1976). The House Committee Report on the bill described a California medical-device statute that was "the most comprehensive" then in existence "as an example of [the sort of state] requirements that [the FDA] should authorize to be continued" if otherwise preempted under § 360k(a). H.R. Rep. No. 94-853, at 45;[7] *see also* 122 Cong. Rec. 5,859 (1976) (remarks of Rep. Waxman) (noting that exemption mechanism would "permit California's progressive program to continue in effect in that State").[8]

As a structural matter, Congress's inclusion of the exemption mechanism for more stringent state regulation counsels for restraint in finding common-law duties to be preempted. Because, as explained below, the exemption process is unavailable as a practical matter for common-law claims,

7. Among other things, the California statute required premarket approval for new medical devices, established good manufacturing practices for medical devices, and authorized inspection of device-manufacturing facilities. *See* H.R. Rep. No. 94-853, at 45.

8. The FDA has granted numerous exemptions to state statutes and regulations that govern the dispensing of hearing aids, *see*, 21 C.F.R. §§ 808.53, 808.57-.101, one of the relatively few areas in which the FDA has promulgated specific federal regulations, *see id.* §§ 801.420-.421.

holding common-law claims such as the Riegels' preempted would give rise to the anomaly that preemption would be broader and more definitive as to common-law tort claims than as to state positive-law regulation, even though the presumption against preemption is especially strong as to longstanding tort causes of action. *See Bates*, 544 U.S. at 449.

The exemption process is virtually unavailable for common-law claims for several reasons. The FDA's regulation makes clear that in ruling on an application for exemption, the agency must consider state law as applied in order to determine whether state law is more stringent than federal law, and whether it is responsive to local conditions. *See* 21 C.F.R. § 808.20(c)(1). Yet it is extremely difficult for a particular State to know in the abstract whether and to what extent state common law is more stringent than federal law with respect to a particular device, or whether its common-law rules are compelled by distinctive local conditions.

Nor would a State be in a position to apply for an exemption from preemption *after* a specific jury verdict on a plaintiff's claim against a particular device, since the preemption defense will prevent such claims from going to the jury in the first place. In any event, since only States or political subdivisions, and not private individuals, may apply for an exemption, a designated government official would have to review every pending or contemplated private tort action to decide whether to seek an exemption.

Thus, under respondent's interpretation of § 360k, common-law duties would be preempted without possibility of exemption, and hence even more decisively than state statutory or regulatory provisions. That result is particularly incongruous in light of the legislative and regulatory history demonstrating clearly that § 360k was targeted at state positive-law enactments rather than common-law duties. For example, the House committee report focused on situations, like California's medical-device statute, where "States ha[d] established their own programs" for

medical-device regulation in the absence of effective federal regulation. H.R. Rep. No. 94-853, at 45. Similarly, an FDA publication released shortly after the MDA's passage envisioned state or local positive enactments as the only possible candidates for preemption: "When *State or local device laws and regulations* are preempted, the State may petition FDA under section 521(b) for an exemption from the 521(a) preemption." U.S. Dep't of Health, Educ., and Welfare, Pub. Health Serv., Food & Drug Admin., Bureau of Med. Devices, *Everything you always wanted to know about the medical device amendments . . . and weren't afraid to ask* 35 (Oct. 1977) (emphasis added).

### B. The MDA's Saving Clause Shows that Congress Took Care to Preserve Manufacturers' Liability For Damages Under State Law Where Approved Devices Prove Unsafe and Cause Injury.

Not only the text and structure of § 360k but also the savings clause of the MDA, 21 U.S.C. § 360h(d), shows that Congress contemplated that state tort law would complement federal device regulation and would not be displaced by it. Section 360h generally describes the FDA's authority to require a device manufacturer to take certain steps — such as notifying the public, repairing or replacing a device, or refunding the purchase price — when the agency concludes that a device already on the market "presents an unreasonable risk of substantial harm to the public health." 21 U.S.C. § 360h(b).

Section 360h is the sole section of the MDA that provides remedies that directly benefit individual patients or consumers. And in that area, Congress took pains to include a saving clause clarifying that the statutory remedies were in addition to, not in lieu of, existing remedies under state law. Accordingly, subsection (d) provides that "[c]ompliance with

an [FDA] order [under § 360h] shall not relieve any person from liability under Federal or State law." This savings clause clearly contemplates tort liability, as shown by its provision that "[i]n awarding damages for economic loss in an action brought for the enforcement of any such liability, the value to the plaintiff in such action of any remedy provided him under such order shall be taken into account."

Accordingly, the "only congressional discussion" about the relationship between the MDA and state tort remedies "indicates that Congress assumed that such remedies would be available." *Silkwood*, 464 U.S. at 251 (addressing the federal Atomic Energy Act). The inclusion of the saving clause and its offset provision demonstrates that Congress did not intend that device regulation under the MDA would supplant traditional state tort law.

## II. The MDA Does Not Evince a Clear and Manifest Congressional Purpose that the Federal Premarket Approval Process Should Replace Postmarket State Product Liability Suits.

The specific preemption issue here is whether the FDA's grant of a PMA to Medtronic's Evergreen Balloon Catheter preempts the Riegels' product liability claims related to the design and labeling of the device. With the enactment of the MDA in 1976, Congress for the first time provided for the FDA to conduct premarket review of medical devices. The statute reserves the PMA process for devices that are most novel and present the greatest potential risks to human safety. *See* 21 U.S.C. § 360c(a)(1)(C). It is implausible that Congress would have intended this untested regime of *ex ante* FDA marketing approval of high-risk medical devices (with no provision of its own to remedy personal injury from marketed devices) to supplant the longstanding role played by the tort system in addressing device safety based on patient experiences after a device's actual use on the market. That is

particularly true since the MDA's passage was spurred by the occurrence of numerous deaths and serious injuries caused by new and technologically sophisticated medical devices in the 1960s and early 1970s. Certainly, in the *ex ante* PMA provisions there is no clear and manifest congressional purpose to preempt postmarketing personal injury claims, as is required to overcome the presumption against preemption. Accordingly, and as explained further below, the PMA process leaves ample room for state product liability suits to continue to protect and compensate medical-device users when approved devices prove to be unreasonably dangerous and cause injury.

1. In order to determine whether § 360k(a) preempts state common law, *Lohr* teaches that it is necessary to identify the specific federal "requirement" claimed to have preemptive effect, and then conduct a "careful comparison" between that federal requirement and the state law in question to determine whether the state law "fall[s] within the intended pre-emptive scope [of the federal requirement]." 518 U.S. at 500. For certain medical devices the MDA indisputably establishes a federal "requirement" that the manufacturer obtain the FDA's approval before marketing the device. That federal PMA requirement has preemptive effect on its state counterparts — i.e., state statutes or regulations that likewise purport to establish a threshold process for obtaining permission to market the device. But the federal PMA requirement does not preempt product liability suits alleging that an approved device was shown to be unreasonably dangerous by events that occurred after the device was sold to consumers or used in treating patients.

There is little doubt that the federal PMA requirement preempts "different or additional State and local premarket approval requirements," absent the grant of an exemption from preemption by the FDA. Exemptions from Federal

Preemption of State and Local Device Requirements: Procedures for Consideration of Applications, 43 Fed. Reg. 18661, 18664 (1978). For example, a state statute or regulation requiring pre-clearance of new devices by a state agency, such as the California medical-device statute discussed above, establishes a requirement "in addition to, or different from" the MDA's premarket approval requirement, and without an exemption is preempted under § 360k(a). Similarly, if a state statute or regulation purported to authorize marketing of a new device without FDA premarket approval, such a provision would be preempted as in direct conflict with federal law.

A grant of a PMA does not, however, establish comprehensive federal "requirements" as to the specifics of a device's design and labeling, thereby preempting all defective-design and failure-to-warn claims alleging that the approved device is unreasonably dangerous. The FDA does not prescribe mandatory standards for a particular device merely by approving the PMA application prepared by the device manufacturer, and does not "require" the device to take any particular form. Moreover, the FDA's grant of a PMA does not explicitly or implicitly reject *other* putative devices with new or different features. FDA approval in no way signifies that federal law disfavors changes to the device's design or labeling. It merely means that the FDA has determined that the device as approved meets the minimum threshold of safety and effectiveness necessary to permit it to be brought to market.[9]

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9. Until recently the FDA itself shared this view as to the import of a PMA grant. *See* Brief for United States as Amicus Curiae in Opposition to Certiorari at 14, *Smiths Indus. Med. Sys., Inc. v. Kernats* (No. 96-1405) (PMA grant signifies that device meets "the applicable federal minimum standards for use and marketing"); *id.* at 15 (general criteria for premarketing approval "establish minimum standards that do not displace state law standards of care or common law duties respecting the medical device").

2. For similar reasons, the prohibition on changing an approved device or its label without supplemental FDA approval, *see* 21 U.S.C. § 360e(d)(6); 21 C.F.R. § 814.39(a), is not tantamount to a federal "requirement" that the device never be improved from its approved specifications. A device manufacturer is not categorically prohibited from changing a previously approved device; rather, the ability to make a change is merely conditioned on FDA approval. Certain kinds of labeling or manufacturing changes that "enhance[] the safety of the device" are presumptively allowed prior to obtaining such approval. 21 C.F.R. § 814.39(d).[10] The existence of a precondition to changing the device is not tantamount to a "requirement" that the device adhere to previously approved specifications, because the manufacturer is free to change the device upon seeking and obtaining approval through a supplemental PMA application. And since the decision whether to seek such approval in the first place is entirely within the manufacturer's control, it would create perverse incentives against device improvement to allow a manufacturer to rest on its initial FDA approval in any future state-law tort suit, on the theory that federal law "required" the manufacturer to maintain the approved design and labeling.

The error of characterizing a grant of a PMA as establishing specific design and labeling requirements is shown by the facts of a recent case in Wisconsin state court. *See Blunt v. Medtronic, Inc.*, No. 2006AP1506, 2007 Wisc. App. LEXIS 667 (Wis. App.

10. Permitted modifications include (1) adding or strengthening a contraindication or warning on the label; (2) adding or strengthening an instruction intended to enhance the safe use of the device; or (3) deleting misleading, false, or unsupported indications. 21 C.F.R. § 814.39(d)(2). The gravamen of the Riegels' failure-to-warn claim is that Medtronic should have strengthened an instruction regarding the inflation limits of its Evergreen Balloon Catheter, a change that would appear to fit the description of those permitted without prior FDA approval.

July 31, 2007). That case concerned a device — an implantable defibrillator — for which Medtronic obtained premarket approval in 2002. Medtronic obtained supplemental approval for a modification of the device a year later. *Id.* at *1-2. However, Medtronic continued to market the device in its original form to clear accumulated inventory. *Id.* at *25 (Fine, J., dissenting). The plaintiff was injured by the original device in 2004, and claimed that the design was defective and the modification was necessary to satisfy the standard of care under state law. *Id.* at *22-23. Medtronic took the position that the plaintiff's claims were preempted, and the Wisconsin state court agreed. *Id.* at *24. That finding of preemption, under *Lohr*, implies that the initial grant of a PMA established a federal requirement to use the original design. But plainly the PMA imposed no such requirement, because at the time of the injury the FDA had also approved the modified design.

If a manufacturer has submitted a supplemental application to make a particular design or labeling change, and the FDA has rejected that application, it might make sense to find preemption of a product liability suit claiming that the specific change was necessary to make the device reasonably safe. But when, as here, a manufacturer has not submitted an application to change the device in any relevant respect, there is no basis for concluding that federal law "requires" the device to take its original form and conflicts with a plaintiff's assertion that the device should have been designed or labeled differently.

3. While the PMA process is more demanding than the premarket notification process considered in *Lohr*, that is not sufficient reason to give broad preemptive effect to the grant of a PMA. *Ex ante* review of a medical device prior to marketing is a predictive process with limitations that make it ill-suited to replace *ex post* adjudication based on the device's actual use in the real world. Given the context in

which the MDA was enacted, the PMA process is best understood as an additional layer of protection to the public that helps prevent some unsafe devices from reaching the market, not a conclusive guarantee of product safety and effectiveness that should discourage further product development or preclude future product liability suits.

Indeed, in 1986, a decade after the MDA's passage, the Director of the FDA's Center for Devices and Radiological Health (which processes PMA applications) acknowledged that the FDA's "system of approving devices isn't perfect, and that unexpected problems [with approved devices] do arise." U.S. Dep't of Health and Human Serv., Public Health Serv., Food & Drug Admin., *The Medical Device Amendments: 10 Years After* 1 (1986). Years later, a House subcommittee report identified "a number of cases in which the FDA [had] approved devices that proved unsafe in use." House Comm. on Energy and Commerce, Subcomm. on Oversight and Investigations, 93rd Cong., *Less Than the Sum of Its Parts: Reforms Needed in the Organization, Management, and Resources of the Food and Drug Administration's Center for Devices and Radiological Health* 1-3 (Comm. Print. 103-N 1993); *see also id.* at 21-24, 31-33.

A principal shortcoming of the PMA process is that the data supporting a PMA application are compiled by the device manufacturer and are often unreliable. In 1993, an FDA committee found flaws in the design, conduct, and analysis of the clinical studies used to support PMA applications that were "sufficiently serious to impede the agency's ability to make the necessary judgments about [device] safety and effectiveness." Food & Drug Admin., Comm. for Clinical Review, *Final Report: Based on a Review of Selected Medical Device Applications* 1-4 (March 1993), *reprinted in Less Than the Sum of Its Parts* at 99-102; *see also The Medical Device Amendments: 10 Years After*, at 1 ("One of the main

reasons [problems arise after approval] is that the data upon which we base our safety and effectiveness decisions isn't perfect."). Similarly, in 1996, the Inspector General of the Department of Health and Human Services reported "serious deficiencies . . . in the clinical data submitted as part of pre-market applications," and further observed that "[w]hen such deficiencies go undetected, medical device approvals may pose health risks for consumers." Office of the Inspector General, U.S. Dep't of Health and Human Services, *Review of the Food and Drug Administration's Processes to Review Medical Device Submissions under the Pre-Market Approval and Investigational Device Exception Programs* 2 (March 1996). The report concluded that changes to processes for auditing data supplied by PMA applicants were necessary to "help prevent unsafe or ineffective critical devices from endangering the public." *Id.* at 10. Moreover, "limitations [are] inherent" in even the best-designed and most reliable clinical studies conducted by manufacturers, since those studies by their nature cannot "duplicat[e] all aspects and hazards of everyday use." *Less than the Sum of Its Parts* at 59.[11]

The MDA's legislative history identifies other limitations in the PMA process that undermine any claim that Congress intended it to replace case-by-case adjudication in tort lawsuits. For example, in some cases, "[a] device may . . .

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11. In a 2004 amicus filing, the United States argued that premarket approval of a particular device is most analogous to an agency adjudication, rather than a rule-making. Brief for United States as Amicus Curiae at 23-24, *Horn v. Thoratec Corp.*, 376 F.3d 163 (3d Cir. 2004). The effect of an agency adjudication in a future lawsuit usually falls under the rubric of preclusion, not preemption. Under ordinary preclusion principles, the FDA's determination in the essentially one-sided PMA process would receive no preclusive effect because the Riegels lacked an adequate opportunity to litigate the issue before the agency. *See U.S. v. Utah Constr. & Mining Co.*, 384 U.S. 394, 422 (1966).

[be] approved based upon an evaluation of the safety and efficacy of certain of its aspects," but it may later "be discovered that other aspects of the product" make it unsafe. H.R. Rep. No. 94-853, at 32. In other situations, technological changes occurring after FDA approval can render unreasonable a safety risk that was reasonable at the time of the FDA's consideration. *Cf.* H.R. Rep. 94-853, at 23 ("[T]here are instances in which a device presented a reasonable risk according to the state of the art at the time of its manufacture which becomes unreasonable due to a change in technology.").

To be sure, the PMA process does not necessarily represent the FDA's only point of contact with an approved device. Largely as a result of amendments passed in the 1990s, beginning with the Safe Medical Devices Act of 1990, Pub. L. 101-629, 104 Stat. 4511, the MDA also addresses postmarket controls of devices as to which the FDA has granted approval, including sections that provide for the FDA to receive reports of injuries caused by a device, require manufacturers to conduct "postmarket surveillance" with respect to devices in some instances, and give the FDA authority to order the recall of a device that has proven unsafe, as well as other similar remedies. *See* 21 U.S.C. §§ 360h, 360i, 360l. But these mechanisms hardly make up for the limitations of the PMA process or eliminate the need for the continuing incentives provided by the threat of tort liability for the marketing of unreasonably dangerous devices. Indeed, a 1997 GAO report found that even when problems with a device are disclosed to the FDA in the postmarketing surveillance process, the agency "does not systematically act to ensure that the reported problems receive prompt attention and appropriate resolution." U.S. General Accounting Office, *Medical Device Regulation: Improvements Needed in FDA's System for Monitoring Problems with Approved Devices* 2 (1997).

4. A ruling that a grant of a PMA does not by itself preempt product liability suits would not render the preemption clause in § 360k(a) a nullity for those devices subject to PMA. As discussed *supra* at 13-14, the federal PMA requirement preempts counterpart state or local market pre-clearance requirements absent the grant of an exemption from preemption. Moreover, the FDA may promulgate regulations establishing specific design or labeling standards for a device or type of devices that have preemptive effect on counterpart state device requirements.

In particular, if the FDA concludes that aspects of the technology underlying a particular device or type of devices is sufficiently mature and that there is an adequate and reliable information base, the agency may promulgate device-specific performance standards through notice-and-comment procedures set out in the MDA. *See* 21 C.F.R. § 861.1(b)(3); S. Rep. No. 94-33, at 13 ("The Committee wishes to make it clear that standards and premarket approval mechanisms are not mutually exclusive."), *reprinted in* 1976 U.S.C.C.A.N. 1070, 1082. If and when it does so, the FDA should of course give careful consideration to the potential consequences of proposed regulations regarding displacement of state law. *See* Executive Order No. 13,132, 64 Fed. Reg. 43,255 (Aug. 4, 1999) (requiring particular sensitivity to federalism concerns in agency rule-makings with preemptive consequences).

Such mandatory prescriptions by regulation, unlike the mere grant of a PMA, may constitute specific federal requirements that preempt different or additional state device standards.[12]

12. The preemptive effect of such a federal regulation would most naturally extend to device-specific state statutes or regulations establishing different or additional requirements for the device. Determining whether the federal regulation would preempt state common-law duties in any particular case would require the "careful comparison" between federal and state law that § 360k(a) demands. *See Lohr*, 518 U.S. at 500, *see also id.* at 502 (holding that the generality of common-law duties usually disqualifies them from being requirements "with respect to" a specific device within the meaning of § 360k(a)).

For example, in 1978, the FDA promulgated regulations establishing labeling requirements and conditions for sale for hearing aids and expressly stated that those regulations preempted state hearing-aid requirements addressing labeling and conditions for sale, unless they were granted exemptions from preemption. *See* 21 C.F.R. §§ 801.420, 801.421; Exemptions from Federal Preemption of State and Local Device Requirements: Procedures for Consideration of Applications, 43 Fed. Reg. 18661, 18662 (May 2, 1978). But even there, the FDA stressed the need for strict congruence in subject matter between the federal and state requirements for preemption to occur, observing that "only [state] requirements relating to [hearing-aid] labeling and conditions for sale were preempted, not all State or local requirements regulating other facets of hearing-aid distribution." *Id.*

All of these reasons show why a grant of a PMA should not preempt state product liability suits, which fulfill a vital and complementary role alongside the PMA process. Such suits provide needed protection and compensation for patients and consumers injured by devices based on actual use in real-world conditions. The *ex ante* PMA procedure, while likely effective in preventing many unsafe devices from reaching the market, cannot ensure the safety of those devices that *are* marketed. Additionally, the threat of product liability suits creates continuing incentives for product manufacturers to improve the safety of their device after receiving a PMA. *See Bates*, 544 U.S. at 451 ("'[T]he specter of damage actions may provide manufacturers with added dynamic incentives to keep abreast of all possible injuries stemming from use of their product so as to forestall such actions through product improvement.'") (quoting *Ferebee v. Chevron Chemical Co.*, 736 F.2d 1529, 1541-42 (D.C. Cir. 1984)).

## III. The FDA's Newly Minted Position on the Preemptive Effect of Premarket Approval Is Entitled to No Weight.

For several reasons, no weight should be afforded to the United States' current litigating position as to the preemptive effect of a PMA, first announced in a 2004 amicus brief, which asserts that a grant of FDA approval represents both a floor and a ceiling as to the safety and effectiveness of an approved device, and displaces all state product liability claims except where it is alleged that the manufacturer failed to adhere to the specifications in his approved application. Brief for United States as Amicus Curiae at 13-31, *Horn*, 376 F.3d 163.

First, this Court generally has not granted deference under *Chevron U.S.A., Inc. v. Natural Resources Defense Council, Inc.*, 467 U.S. 837 (1984), to an agency's position as to the preemptive scope of a federal statute. *See Lohr*, 518 U.S. at 512 (O'Connor, J., concurring in part and dissenting in part) ("It is not certain that an agency regulation determining the pre-emptive effect of *any* federal statute is entitled to deference."); *cf. Smiley v. Citibank (South Dakota), N.A.*, 517 U.S. 735, 743-44 (1996) (assuming without deciding that the question of a statute's preemptive effect "must always be decided *de novo* by the courts"). There are good reasons not to afford *Chevron* deference in this area. Not only does preemption analysis require application of complex legal doctrines, a task at which the courts are most expert, but preemption of state law also raises sensitive questions of federalism, which agencies are ill-equipped to resolve. Perhaps for that reason, this Court recently relied on its own interpretation of a federal statute's preemptive effect, rather than relying on deference to an agency's similar position or even deciding what degree of deference might be due that position. *See Watters v. Wachovia Bank, N.A.*, 127 S. Ct. 1559, 1572 & n.13 (2007). As Justice Stevens observed

in dissent in that case, "when an agency purports to decide the scope of federal preemption, a healthy respect for state sovereignty calls for something less than *Chevron* deference." *Id.* at 1584 & n.25 (Stevens, J., dissenting).

To be sure, this Court has on occasion, including in *Lohr* itself, looked to an agency's views to inform the application of preemption doctrine to a particular issue, especially when the analysis implicates technical matters. *See* 518 U.S. at 495-96; *see also Geier v. Am. Honda Motor Co.*, 529 U.S. 861, 883 (2000) (giving "some weight" to agency opinion on conflict preemption). But it has not done so where following the agency's position would effectively nullify the strong presumption against preemption. In *Lohr*, the Court consulted the FDA's regulation, 21 C.F.R. § 808.1, for guidance in identifying a narrow construction of § 360k(a) that was fully consonant with the presumption against preemption. 518 U.S. at 495-96. And in *Geier*, the Court did not hold the presumption against preemption to be applicable; therefore, giving weight to the agency's position favoring preemption did not require overruling the presumption.

As this Court ruled in *Bates*, the presumption against preemption, where it applies, compels a court to adopt the construction of an express preemption clause that disfavors preemption of state law, even where the United States, on behalf of an agency, files a brief asserting a different view. 544 U.S. at 449; *see also id.* at 436-37 & n.7. The presumption requires a clear indication of congressional purpose for preemption to occur, and an administrative agency cannot supply the required clear statement where Congress has not. *See Desiano v. Warner-Lambert & Co.*, 467 F.3d 85, 97 n.9 (2d Cir. 2006) ("[A]n agency cannot supply, on Congress's behalf, the clear legislative statement of intent required to overcome the presumption against preemption."). This Court has embraced a similar argument

in the context of the constitutional-avoidance doctrine, which is an analogous clear-statement principle that trumps even *Chevron* deference and requires construction of an ambiguous statute to avoid constitutional questions, notwithstanding a contrary agency interpretation. *See Solid Waste Agency of N. Cook County v. U.S. Army Corps of Engineers*, 531 U.S. 159, 172 (2001); *Edward J. DeBartolo Corp. v. Fla. Gulf Coast Bldg. & Constr. Trades Council*, 485 U.S. 568, 574-577 (1988).

A second and independent reason for giving little or no weight to the FDA's current view of preemption is that it was developed and asserted in the course of litigation. Unlike 21 C.F.R. § 808.1, which remains in effect and points away from any finding of preemption in this case, *see supra*, at 7-8, the agency's present view favoring preemption has been asserted only in legal briefs, and was not developed through notice-and-comment procedures that would have afforded Members of Congress, the States, and other interested persons an opportunity to participate. The FDA's failure to proceed by notice-and-comment procedures is in substantial tension with recent executive orders directed at correcting the tendency of agencies to overlook federalism principles when formulating views on preemption. *See, e.g.*, Executive Order No. 13,132, §§ 4, 6, 64 Fed. Reg. 43,255, 43,357-58 (Aug. 4, 1999) (requiring consultation with States and an opportunity for state and local officials to participate in rulemaking or adjudicatory proceedings with potentially preemptive consequences).

While in *Geier* this Court gave weight to an agency position on preemption expressed in legal briefs, this Court stressed that the agency had maintained its view "consistently over time." 529 U.S. at 883. That is not true in this case. Until 2004, the FDA considered its grant of a PMA *not* to preempt state product liability suits for injuries to patients or consumers caused by the device. *See* Brief for United States as Amicus Curiae in Opposition to Certiorari, *Kernats* (No. 96-1405). The FDA's prior approach reflected its longstanding view since enactment

of the MDA, also embodied in 21 C.F.R. § 808.1, that "the scope of preemption under [§ 360k] should be interpreted narrowly, with a presumption against preemption, . . . . particularly when the effect of preemption would be to override a state scheme offering greater consumer protection." Margaret Jane Porter, Chief Counsel of the Food & Drug Admin., *The Lohr Decision: FDA Perspective and Position*, 52 Food Drug L.J. 7, 7 (1997). The FDA has now turned its back on these principles with little explanation; indeed, the brief announcing the FDA's new position did not mention the presumption against preemption, or explain how the agency's recent conclusions could be reconciled with it.

A third reason to reject the FDA's current view of preemption in this case is that it is based on an anachronism. The FDA now seeks to characterize a grant of a PMA as prescribing specific requirements that establish both a floor and a ceiling as to the design and labeling of an approved device. Brief for United States as Amicus Curiae at 15, 29, *Horn*, 376 F.3d 163. But that was not the agency's view when it approved Medtronic's Evergreen Balloon Catheter for marketing in 1994 (or, for that matter, when the device was used in treating Charles Riegel in 1996). At that time, the FDA thought it was passing only on the question whether the Evergreen Catheter was minimally safe, and believed that state product liability suits would operate to provide strong and continuing incentives for Medtronic to seek to improve the device after marketing. Even if, contrary to the arguments above, the FDA could properly treat future PMA grants as preemptive, it would be rewriting history to characterize the 1994 PMA grant for the Evergreen Catheter as prescribing specific device requirements that establish both a safety floor and ceiling. That is simply not what the FDA thought it was doing in 1994.

## CONCLUSION

The judgment of the court of appeals should be reversed.

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156 a

41

No. 06-179

IN THE

# Supreme Court of the United States

DONNA S. RIEGEL, Individually and as Administrator of the Estate of Charles R. Riegel,

*Petitioner,*

*v.*

MEDTRONIC, INC.,

*Respondent.*

ON WRIT OF CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE SECOND CIRCUIT

## BRIEF OF PRODUCT LIABILITY ADVISORY COUNCIL, INC. AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT


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## TABLE OF CONTENTS


| | Page |
|---|---|
| TABLE OF CITED AUTHORITIES ..... | iii |
| INTEREST OF *AMICUS CURIAE* ..... | 1 |
| SUMMARY OF ARGUMENT ..... | 2 |
| ARGUMENT ..... | 5 |
| I. THE PRE-MARKET APPROVAL PROCESS IMPOSES FEDERAL REQUIREMENTS THAT PREEMPT STATE LAWS UNDER SECTION 360k OF THE MDA. ..... | 5 |
| A. The Court Should Implement the Plain Language and Evident Intent of the Express Preemption Provision in the MDA. ..... | 5 |
| B. Irrespective of Any Presumption, the Pre-Market Approval Process Imposes Requirements that Preempt State Law. ..... | 8 |
| C. Irrespective of Any Presumption, State Product Liability Claims Are Different or Additional State Requirements Within the Meaning of 21 U.S.C. § 360k(a). ..... | 17 |

*Contents*

*Page*

II. A FINDING THAT THE PMA PROCESS PREEMPTS STATE PRODUCT LIABILITY CLAIMS WOULD PROMOTE THE PURPOSES OF THE MDA. ..... 20

CONCLUSION ..... 25

APPENDIX A — CORPORATE MEMBERS OF THE PRODUCT LIABILITY ADVISORY COUNCIL AS OF 8/6/2007 .... 1a

## TABLE OF CITED AUTHORITIES


Page

**CASES**

*Barnett Bank of Marion County, N.A. v. Nelson*,
517 U.S. 25 (1996) ..... 6

*Bates v. Dow Agrosciences LLC*,
544 U.S. 431 (2005) ..... *passim*

*Brooks v. Howmedica, Inc.*,
273 F.3d 785 (8th Cir. 2001) ..... 23

*Cipollone v. Liggett Group, Inc.*,
505 U.S. 504 (1992) ..... 18

*Egelhoff v. Egelhoff ex rel. Breiner*,
532 U.S. 141 (2001) ..... 7

*English v. Gen. Elec. Co.*,
496 U.S. 72 (1990) ..... 6

*Horn v. Thoratec*,
376 F.3d 163 (3d Cir. 2004) ..... 23

*Lorillard Tobacco Co. v. Reilly*,
533 U.S. 525 (2001) ..... 7

*Medtronic, Inc. v. Lohr*,
518 U.S. 470 (1996) ..... *passim*

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504 U.S. 374 (1992) ..... 5

*Cited Authorities*

*Page*

*Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154 (3d Cir. 2001) ..... 21

*Retail Clerks v. Schermerhorn*, 375 U.S. 96 (1963) ..... 7

**STATUTES**

21 U.S.C. § 332 ..... 16

21 U.S.C. § 333(g) ..... 16

21 U.S.C. § 334 ..... 16

21 U.S.C. § 335 ..... 16

Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§ 360c, *et seq.* ..... 2

21 U.S.C. § 360c(b) ..... 13

21 U.S.C. § 360c(a)(3)(D) ..... 12

21 U.S.C. § 360e(c) ..... 10

21 U.S.C. § 360e(c)(2) ..... 13

21 U.S.C. § 360e(d) ..... 4

*Cited Authorities*


| | Page |
|---|---|
| 21 U.S.C. § 360e(d)(1)(A) | 13 |
| 21 U.S.C. § 360e(d)(3) | 13 |
| 21 U.S.C. § 360e(e) | 15 |
| 21 U.S.C. § 360h(a) | 15 |
| 21 U.S.C. § 360h(b) | 15 |
| 21 U.S.C. § 360h(b)(2)(C) | 15 |
| 21 U.S.C. § 360h(e) | 15 |
| 21 U.S.C. § 360k(a) | 2, 4, 5, 9, 17 |
| Food and Drug Administration Amendments Act, Pub. L. No. 110-85, 121 Stat. 823 (2007) | 23 |
| **REGULATIONS** | |
| 21 C.F.R. Part 17 | 16 |
| 21 C.F.R. Part 810 | 15 |
| 21 C.F.R. § 812.1 | 10 |
| 21 C.F.R. §§ 812.27 | 11 |
| 21 C.F.R. § 814.20 | 10 |

*Cited Authorities*


| | *Page* |
|---|---|
| 21 C.F.R. § 814.20(b)(6)(ii) | 10 |
| 21 C.F.R. § 814.37(b) | 13 |
| 21 C.F.R. § 814.39 | 15, 22 |
| 21 C.F.R. § 814.42 | 12 |
| 21 C.F.R. § 814.44 | 13 |
| 21 C.F.R. § 814.44(e) | 14 |
| 21 C.F.R. § 814.44(e)(1) | 14 |
| 21 C.F.R. § 814.44(f) | 14 |
| 21 C.F.R. § 814.45 | 13 |
| 21 C.F.R. § 814.46 | 15 |
| 21 C.F.R. § 814.80 | 15 |


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*Page*

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Food and Drug Administration, "Goals and Initiatives for the IDE Program," 1995 WL 17210906 (July 12, 1995) ..... 11

Food and Drug Administration, "Learn about Medical Device Recalls," www.fda.gov/cdrh/recalls/learn.html ..... 16

Mark Heller, 1 Guide to Medical Device Regulation ¶ 732 (1999) ..... 13, 14

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*Page*

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W. Kip Viscusi, Reforming Products Liability (1991) ..... 21

This brief is filed on behalf of the Product Liability Advisory Council, Inc. as *amicus curiae* in support of Respondent, with the written consent of the parties.[1]

## INTEREST OF *AMICUS CURIAE*

*Amicus Curiae* Product Liability Advisory Council, Inc. ("PLAC") is a nonprofit association with more than 120 corporate members representing a broad cross-section of American and international product manufacturers.[2] These companies seek to contribute to the improvement and reform of law in the United States and elsewhere, with emphasis on the law governing the liability of manufacturers of products. PLAC's perspective derives from the experiences of a corporate membership that spans a diverse group of industries in various facets of the manufacturing sector. Several hundred of the leading product liability defense attorneys in the country are also sustaining (nonvoting) members of PLAC. Since 1983, PLAC has filed more than 800 briefs as *amicus curiae* in both state and federal courts, including at least 69 briefs in this Court, presenting the broad perspective of product manufacturers seeking fairness and balance in the application and development of the law as it affects product liability.

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[1] Copies of those consents have been filed with the Clerk of the Court. No counsel for a party in this case authored this brief in whole or in part, and no person or entity other than *amicus curiae*, its members, or its counsel made a monetary contribution to the preparation or submission of this brief.

[2] A list of PLAC's current corporate membership is included as Appendix A to this brief.

PLAC is well situated to address the issues in this case. Its members often have confronted the interplay between the duties imposed by federal regulatory authorities and the common law standards applied in product liability cases. PLAC therefore can offer a more in-depth and broader perspective on preemption than the parties may provide.

## SUMMARY OF ARGUMENT

In the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. §§ 360c, *et seq.*, Congress expressly preempted requirements imposed under state law that differ from or add to federal requirements applicable to a medical device. *See* 21 U.S.C. § 360k(a). For devices subject to the Pre-market Approval ("PMA") process, the Food and Drug Administration ("FDA") requires the manufacturer to do certain things, for example, to follow a specific design and to use particular language in the labeling. Petitioner argues that state law may impose a duty on the manufacturer – a requirement in the plainest sense of the word – to do or say something different. That position clashes with the clear language of the MDA.

Petitioner and her *amici* nonetheless seek refuge in the "presumption against preemption." But if applicable at all, a canon of construction is at most an aid in discerning the intent of Congress, not an avenue around it. Where the Congressional will is plain, this Court's task is to effectuate it. Here, based on the ordinary meaning of the words Congress used, the PMA process for medical devices imposes federal requirements specifically applicable to each approved device. The PMA

process entails close collaboration between the Food and Drug Administration and the applicant seeking approval. That collaboration, specifically mandated by statute, involves active give and take between FDA and the applicant. Through this process, FDA shapes the application, takes a hand in interpreting the relevant studies, specifies aspects of the design of the product, and often dictates the language of the label. In other words, even before approving the application, FDA imposes requirements applicable to the device. Moreover, once FDA does approve the application, the PMA imposes binding, highly particularized requirements applicable to the device. An applicant may not materially change the device, or its labeling, or the process by which the device is manufactured without FDA's concurrence. Petitioner's argument that the PMA process does not impose "specific substantive requirements" bears no relationship to reality.

On the other side of the ledger, state lawsuits under common law or consumer protection statutes likewise impose requirements applicable to medical devices. Indeed, this Court has repeatedly recognized, as recently as in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), that state common law imposes "requirements" for purposes of the express preemption provisions. *See id.* at 443 ("[T]he term 'requirements' . . . reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties."). Nonetheless, Petitioner argues that her common law causes of action somehow transcend preemption because they are of general applicability, while preemption under the MDA is confined to product-specific regulations or statutes. The language of the MDA is not limited to

product-specific statutes and regulations. The preemption provision applies to *"any"* requirement imposed under state law that is different from or in addition to a federal requirement. *See* 21 U.S.C. § 360k(a). The word "any" is easily understood. It is encompassing. Moreover, the common law duties at issue here are not ones, for example, governing the commercial transaction in which the device is sold. Petitioner seeks to regulate the design and labeling of the device itself. Just as the overarching FDA requirement that a device be safe and effective for its intended use, *see* 21 U.S.C. § 360e(d), translates to particularized requirements applicable to a specific device through a PMA, a common law duty translates to particularized requirements applicable to a specific device through a lawsuit.

In enacting the express preemption provision in the MDA, Congress determined that imposition of state requirements in addition to or different from federal regulation would undermine public health. That judgment was correct. As FDA has stated in this Court, in Courts of Appeals, and in the preamble to regulations, allowing state judges and juries to second-guess the FDA's approval of PMAs, or to dictate different requirements than FDA has imposed, impedes FDA's ability to fulfill its mandate in furtherance of public health. This Court, therefore, should uphold the nearly unanimous conclusion of the Courts of Appeal that the Medical Device Amendments preempt state lawsuits challenging PMA-approved devices.

## ARGUMENT

### I. THE PRE-MARKET APPROVAL PROCESS IMPOSES FEDERAL REQUIREMENTS THAT PREEMPT STATE LAWS UNDER SECTION 360k OF THE MDA.

#### A. The Court Should Implement the Plain Language and Evident Intent of the Express Preemption Provision in the MDA.

This case requires a straightforward exercise in statutory construction. As this Court has stated, analysis of preemption begins "with the language employed by Congress and the assumption that the ordinary meaning of that language accurately expresses the legislative purpose." *Morales v. Trans World Airlines Inc.*, 504 U.S. 374, 383 (1992). In the MDA, Congress included a provision expressly preempting state law. With regard to medical devices used in human patients, that provision bars states from "establish[ing] or continu[ing] in effect . . . any requirement . . . which is different from, or in addition to, any requirement applicable under this chapter to the device." 21 U.S.C. § 360k(a).

Petitioner contrives numerous reasons why this language does not mean what it pointedly says – that states cannot impose *any* requirement that differs from or adds to a requirement the MDA imposes on a device. In particular, Petitioner suggests that courts so disfavor preemption that Congress must proclaim its intention to preempt with a clarity seemingly beyond what the English language could muster. Congress bears a heavy burden in legislating to preempt state law, Petitioner

asserts, and this Court accedes to such an effort only in the most compelling circumstances. *See* Pet. Br. 17-19. If Petitioner means to imply that this Court should do anything other than divine and implement the Congressional intent embodied in a statutory provision expressly preempting state legal requirements, that is not the role this Court has set for itself. To be sure, Congress ought to speak clearly when preempting state laws. But where, as here, it has done so, the Court has long recognized that the job of the Judiciary is to interpret the statute as Congress intended – not to override Congress or to impose the Court's own preferences. *See Barnett Bank of Marion County, N.A. v. Nelson*, 517 U.S. 25, 30-31 (1996) ("This question is basically one of congressional intent. . . . Sometimes courts, when facing the pre-emption question, find language in the federal statute that reveals an explicit congressional intent to pre-empt state law."); *English v. Gen. Elec. Co.*, 496 U.S. 72, 79 (1990) ("[W]hen Congress has made its intent known through explicit statutory language, the courts' task is an easy one.").

A presumption, if applicable at all, is no more than a tool for resolution of doubt. It operates at the margins of decision-making, where the Court must choose between equally plausible interpretations of a Congressional enactment – akin to the sandlot rule that a tie goes to the runner. If the call is that close, the Court might fairly presume that Congress would not cavalierly override state laws. *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996). But at least where the language of the statute is clear, or where the legislative purpose is discernible even though the statutory language is imprecise, the proper role for an Article III court is to

effectuate that congressional purpose, not to penalize Congress for imprecise or inelegant draftsmanship. As the Court has explained:

> "[A]nalysis of the scope of [a] statute's pre-emption is guided by [the] oft-repeated comment, initially made in *Retail Clerks v. Schermerhorn*, 375 U.S. 96, 103 . . . (1963), that '[t]he purpose of Congress is the ultimate touchstone' in every pre-emption case. . . . As a result, any understanding of the scope of a pre-emption statute must rest primarily on 'a fair understanding of *congressional purpose*.'"

*Id.* at 485-86 (internal citations omitted); *Egelhoff v. Egelhoff ex rel. Breiner*, 532 U.S. 141, 151 (2001) ("There is indeed a presumption against pre-emption in areas of traditional state regulation such as family law. . . . But that presumption can be overcome where, as here, Congress has made clear its desire for pre-emption."); *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525, 542 (2001) ("Our analysis begins with the language of the statute."). Thus, a presumption against preemption cannot justify reading the word "any" in Section 360k as "some," or inserting the word "specific" when Congress did not use it, or determining contrary to ordinary understanding that a state law "duty" or a compulsory PMA specification is not a "requirement." No presumption for purposes of statutory construction can supersede either the words or the intent of Congress.

*Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), is entirely in accord. The Court found there that the Federal Insecticide, Fungicide, and Rodenticide Act

("FIFRA") did not preempt certain state law causes of action and potentially preempted others. In making that determination, the Court did not marshal a presumption to trump the language of the statute. Indeed, the Court found that the language of the statute compelled the result as it was "the *only one* that makes sense of each phrase in" the preemption provision. *Id.* at 449 (emphasis supplied).

In sum, this Court should not take the detour Petitioner urges from the plain wording of this statute.

### B. Irrespective of Any Presumption, the Pre-Market Approval Process Imposes Requirements that Preempt State Law.

In *Medtronic v. Lohr*, a majority of this Court held that the 510(k) pre-market notification process did not impose federal requirements within the meaning of the MDA's preemption provision. 518 U.S. at 493-94. But Justice Stevens's opinion for the majority on this issue carefully distinguished the pre-market *notification* process from the pre-market *approval* process. *Id.* at 478-80 ("The § 510(k) notification process is by no means comparable to the PMA process. . . ."). Under the 510(k) pre-market notification procedure, a device may be marketed if it is "substantially equivalent" to a pre-existing device, even where the pre-existing device was not approved through the PMA process. Thus, in the Court's view, FDA "did not 'require' Medtronic's pacemaker to take any particular form for any particular reason; the agency simply allowed the pacemaker, as a device substantially equivalent to one that existed before

1976, to be marketed without running the gauntlet of the PMA process." *Id.* at 493-94.

By contrast, the PMA process is all about imposing design, manufacturing, labeling, and other requirements on a particular device. Petitioner's argument to the contrary defies both logic and practical reality. For one, Petitioner concedes that a regulation dictating a particular design for a device would impose a specific requirement capable of preempting a different or additional state requirement. *See* Pet. Br. 25-26. Thus, if the FDA had adopted a regulation requiring that the balloon component of the device at issue here, a balloon catheter, be yellow, that would in Petitioner's view qualify as a federal requirement within the meaning of 21 U.S.C. § 360k(a). But – on Petitioner's reasoning – if FDA dictated that same condition during the PMA process, it would not be a requirement. Either Petitioner is elevating form over substance – defying logic – or she is maintaining that FDA does not impose such conditions in the PMA process – denying reality.

That regulations generally applicable to Class III devices set the boundaries of the PMA process does not mean that FDA refrains from imposing any specific requirements within those boundaries on devices undergoing review. The controlling standard, requiring that the PMA application demonstrate a reasonable assurance of safety and effectiveness, is formidable. As the Court recognized in *Lohr*, "Despite its relatively innocuous phrasing, the process of establishing this 'reasonable assurance' . . . is a rigorous one." 518 U.S. at 477. In particular, those rigors of the PMA process include numerous, intricate, burdensome requirements.

The parties have addressed that process and the requirements it imposes, but certain aspects merit emphasis.

The MDA and the implementing regulations require manufacturers to submit, before a new Class III device can be marketed, a detailed application that describes the device, its functional components, principles of operation, manufacturing processes, clinical and non-clinical laboratory studies, and proposed labeling. 21 U.S.C. § 360e(c); 21 C.F.R. § 814.20. But it would be wrong to assume, as *amicus* AARP does, that because the manufacturer submits the application and draft labeling to FDA, the Agency is merely a passive receptacle, accepting or rejecting what the applicant proposes. In fact, the PMA process engenders active give and take between FDA and the applicant – or more aptly, a cycle of demands by FDA and compliance by the applicant – starting well before the PMA is filed. Through that process, FDA imposes requirements early and often.

FDA's specific requirements commence essentially upon conception of a new device. The Agency requires that most PMAs include data from investigations in humans – that is, "clinical investigations" – to establish the safety and effectiveness of the device. *See* 21 C.F.R. § 814.20(b)(6)(ii). Because it is otherwise illegal to distribute an unapproved medical device in interstate commerce, a person seeking to initiate a clinical investigation of an unapproved device must first seek FDA permission in an application for an Investigational Device Exemption ("IDE"). 21 C.F.R. § 812.1. Each IDE application must include a complete report of prior

investigations of the device, a description of the manufacturing procedures and quality controls used in producing the device, copies of all labeling for the device, and detailed information on the proposed clinical investigations. 21 C.F.R. §§ 812.27. To avoid rejections of IDE applications, FDA has procedures that communicate requirements to sponsors before the studies begin. These include a "pre-IDE" meeting, which "increase[s] the sponsor's understanding of various FDA requirements, regulations, and guidance documents and thus lead[s] to more complete original IDE applications." Food and Drug Administration, "Goals and Initiatives for the IDE Program," 1995 WL 17210906 (Jul. 12, 1995).

Even before submission of the actual IDE, FDA "encourages" sponsors to submit a "pre-IDE application" with preliminary information for FDA to review. *Id.* This submission allows FDA staff to "provide informal guidance to the industry on troublesome parts of the IDE application before the official submission is made." *Id.* Since FDA is the decider on the application, its "informal guidance" is more than just suggestive. Further, FDA has frequent communication with IDE sponsors during its review, so that "deficient information can be addressed within fewer review cycles." *Id.* Thus, both the pre-IDE and IDE review processes are interactive. FDA communicates its detailed requirements to sponsors from the outset, well before any PMA application is prepared. The sponsors attempt to meet them. The results of these interactions shape the product's design and labeling, which FDA ultimately must approve before any PMA device can be marketed.

Much of this was the case even before *Medtronic v. Lohr*. And since 1997, Section 513(a)(3)(D) of the Food Drug and Cosmetic Act, 21 U.S.C. § 360c(a)(3)(D), has dictated an additional process for "early collaboration" meetings between FDA and potential PMA applicants. As described in an FDA guidance document for industry and FDA staff, "Early Collaboration Meetings Under the FDA Modernization Act," those meetings occur after the pre-IDE meeting but before the applicant submits the PMA. *See* Food and Drug Administration, "Early Collaboration Meetings Under the FDA Modernization Act (FDAMA); Final Guidance for Industry and for CDRH Staff," 2001 WL 34768220 (Feb. 28, 2001). The purpose is "to facilitate interaction between FDA and applicants and provide clear *direction* for testing and development of those devices requiring clinical investigations to support marketing." *Id.* (emphasis supplied). To request an early collaboration meeting – again before the PMA is even filed – the applicant must include a detailed description of the device and the proposed conditions of use, information regarding the expected performance of the device, and a proposed plan for the clinical evaluation of the device, including a detailed clinical protocol. *See id.* The goal of the meeting is to reach consensus on exactly what FDA will require in a specific PMA. *See id.* In other words, it is another opportunity for FDA informally to impose device-specific requirements. If the applicant does not comply, the Agency will not accept the PMA for filing.

Once the applicant overcomes the preliminary hurdles, complies with FDA's required conditions, and submits a PMA that the Agency accepts for filing, FDA reviews the submission at length. *See* 21 C.F.R. § 814.42.

The review often involves an assessment by an advisory committee of outside experts, which typically holds a public meeting before providing its recommendations to FDA on the approvability of the PMA. *See* 21 U.S.C. §§ 360c(b), 360e(c)(2); 21 C.F.R. § 814.44. During this review, the interaction continues between FDA and the applicant to ensure that the applicant satisfies FDA's terms and conditions. For example, the FDA and the applicant will meet no later than one hundred days after the filing of the PMA to review the status of, and any deficiencies in, the PMA. 21 U.S.C. § 360e(d)(3). FDA can and does use this opportunity to impose additional requirements applicable to the device. *See* Mark Heller, 1 Guide to Medical Device Regulation ¶ 732 (1999) (applicant and FDA may develop an action plan at the hundredth day meeting or discuss options "related to premarket versus postmarket requirements").

At the conclusion of its review, FDA decides whether to approve the device for marketing. 21 U.S.C. § 360e(d)(1)(A); 21 C.F.R. § 814.45. Again, contrary to the suggestion of Petitioner's *amici*, the Agency is not confined to a "take it or leave it" choice – to accept or reject without alteration whatever the applicant proposes. Instead, the FDA may opt to impose still more requirements before approving the PMA. First, the Agency can request a manufacturer to amend its application "with any information regarding the device that is necessary for FDA or the appropriate advisory committee to complete the review of the PMA or PMA supplement." 21 C.F.R. § 814.37(b). If, for example, FDA concludes that a particular change in the design or labeling of the device is appropriate, it can use these

"requests" to make that change a requirement for approval of the PMA. *See id.*

Second, instead of approving or rejecting an application outright, FDA can issue an "approvable letter" when "the agency believes it can approve the application if specific additional information is submitted or *specific conditions* are agreed to by the applicant." 21 C.F.R. § 814.44(e) (emphasis supplied); *see also* Heller, *supra*, ¶ 740 ("The FDA may impose post-approval requirements on a device whose premarket approval (PMA) application it approves; in fact, the FDA Modernization Act of 1997 directed the Agency to balance premarket requirements with postmarket controls."). The approvable letter details the information the manufacturer must submit or the conditions it must satisfy. 21 C.F.R. § 814.44(e)(1).

Third, the Agency can also issue a "not approvable" letter requiring specific changes. This letter describes the deficiencies in the application, and "where practical, will identify measures *required* to place the PMA in approvable form." 21 C.F.R. § 814.44(f) (emphasis supplied). Thus, as the overseer of the PMA process, FDA has the power not only to say "yes" or "no," but also to say "yes, but" and "no, but," thereby imposing additional requirements that may subsequently lead to pre-market approval.

Even if FDA did not impose specific requirements by shaping the PMA process in this manner, once the PMA is approved, its specifications become requirements from which the manufacturer cannot deviate without FDA's concurrence. The applicant is

*required* to comply with the design specified in FDA's PMA. *See* 21 C.F.R. § 814.39. The applicant is *required* to adhere strictly to the labeling specified in the PMA. And the applicant is *required* to follow the manufacturing and other procedures specified in the PMA. 21 C.F.R. § 814.80 ("A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device."). Any changes require detailed documentation, reporting, *and*, most importantly, further FDA approval. 21 C.F.R. § 814.39.

If the manufacturer fails to comply with these requirements, or if the device proves to be unsafe, FDA has a wide range of remedies. It can:

- Revoke or suspend the approval of the device. 21 U.S.C. § 360e(e); 21 C.F.R. § 814.46.

- Order the manufacturer to recall, repair, or replace the device. 21 U.S.C. § 360h(b), (e); 21 C.F.R. Part 810.

- Order the manufacturer to refund the purchase price of the device to customers. 21 U.S.C. § 360h(b)(2)(C).

- Require the manufacturer to issue a notice to all health professionals who prescribe or use the device and any other person, including device users, when necessary to eliminate an unreasonable risk of harm posed by a device. 21 U.S.C. § 360h(a); 21 C.F.R. Part 810.

- Seize the device. 21 U.S.C. § 334.

- Obtain a court injunction prohibiting the manufacture or marketing of the device. 21 U.S.C. § 332.

- Impose civil money penalties on the manufacturer. 21 U.S.C. § 333(g); 21 C.F.R. Part 17.

- Recommend criminal prosecution of the manufacturer or its executives. 21 U.S.C. § 335.

It is misleading to suggest that, because FDA does not invoke these powers as frequently as Petitioner's *amici* might wish, the remedies are toothless and the Agency is incapable of imposing requirements on manufacturers. Given FDA's authority and the regulatory tools in its arsenal, its whisper is as commanding as a shout by others. For example, FDA needs only to "ask" a manufacturer to conduct a recall. A refusal, necessitating a recall order by the Agency, is highly unusual. *See* Food and Drug Administration, "Learn about Medical Device Recalls," www.fda.gov/cdrh/recalls/learn.html ("Legally, FDA can require a company to recall a device. . . . However, in practice, FDA has rarely needed to require a medical device recall.").

In sum, the PMA process is an extended, iterative dialogue that both derives from and results in a highly particularized set of requirements for Class III devices.[3]

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[3] These detailed requirements distinguish this case from *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005). In *Bates*, (Cont'd)

Manufacturers must abide by these requirements or risk severe sanctions. Under the plain language of the statute, these customized requirements preempt any additional or different requirements under state law.

### C. Irrespective of Any Presumption, State Product Liability Claims Are Different or Additional State Requirements Within the Meaning of 21 U.S.C. § 360k(a).

The plain language of Section 360k, barring states from imposing "any requirement" different from or in addition to those under the MDA, encompasses "requirements" imposed by state common law. As Medtronic's brief shows, a majority of this Court agreed in *Lohr* – and in subsequent cases.

The argument of Petitioner and her *amici* that tort suits do not impose requirements because they merely result in the payment of damages is illogical, inconsistent with this Court's decisions, and a reprise of arguments

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(Cont'd)

the plaintiffs alleged that their use of Dow's EPA-registered pesticide in acidic soil resulted in damage to their crops and that Dow had failed to warn of this prospect. Dow argued that FIFRA preempted the claims because EPA had not required statements about efficacy in the labeling. The Court, in finding that preemption did not apply to a number of the plaintiffs' claims, stated that, in accordance with EPA's practice after 1972, "the EPA never passed on the accuracy of the statement in Strongarm's original label recommending the product's use 'in all areas where peanuts are grown.'" *Id.* at 440. By contrast, the FDA meticulously reviews and approves each specific claim in the labeling of a medical device approved through the PMA process.

that the Court has repeatedly rejected. The predicate to paying damages is a breach of a duty – or requirement – under state law. This Court has explained, as recently as *Bates*, that "requirements" included state common-law duties. *See* 544 U.S. at 443 ("[T]he term 'requirements' . . . reaches beyond positive enactments, such as statutes and regulations, to embrace common-law duties."); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 521 (1992) (plurality opinion) ("The phrase '[n]o requirement or prohibition' sweeps broadly and suggests no distinction between positive enactments and common law; to the contrary, those words easily encompass obligations that take the form of common-law rules.").

Petitioner and her *amici* argue further that Congress could not have intended to preempt tort lawsuits because it did not mention them in the legislative history. Inferences from legislative silence are perilous indeed, and the asserted inference is particularly unwarranted here, where the preemption extends to only devices subject to PMA approval – a tiny minority of the devices subject to FDA regulation[4] – and then only when state law imposes requirements different from or in addition to state requirements. In *Bates*, the Court noted that the legislative history of FIFRA contained no discussion of preempting state tort suits. *See* 544 U.S. at 452 n.26. Nonetheless, the Court held that, by its express terms, FIFRA preempts state law

[4] *See Lohr*, 518 U.S. at 477 ("Not all, nor even most, Class III devices on the market today have received premarket approval . . . ."). For example, in fiscal year 2005, FDA received just 43 original PMA applications, but received 3130 § 510(k) notifications. *See* FDA Office of Device Evaluation, Annual Report Fiscal Year 2005.

claims for fraud and failure to warn – both liability theories of general applicability to products of any kind – insofar as the claims would impose labeling or packaging requirements that differ from, or add to, the labeling and packaging requirements of FIFRA itself. *Id.* at 452-54.

In any event, the argument of Petitioner and her *amici* accords more importance to what was *not* said in committee reports or in debate than what *was* said in the statute itself. As all the Justices agreed in *Lohr*, Section 360k shows that Congress clearly intended to preempt state law. Congress expressed its intent as to the scope of preemption in the language of the statute. In specifying which state law was preempted, Congress picked two key words: "any" and "requirements." It could hardly have chosen broader terms.

This case illustrates precisely how state tort suits result in particularized state-law "requirements" within the meaning of Section 360k. Petitioner claims that the Medtronic device used in Mr. Riegel's angioplasty procedure was defectively and negligently designed and tested because the balloon burst during the operation. Pet. App. 4a. To prevail on these claims, as well as their claim regarding inadequate labeling, Plaintiffs would have to show that what Medtronic did in designing and labeling the device violated the company's duties under state law. In other words, Petitioner must establish that Medtronic should have, but failed to, design the device to withstand pressures higher than the 10 atmospheres ("atm") to which Mr. Riegel's surgeon inflated the balloon, *id.* at 4a-5a, and alter the product labeling to strengthen further the existing warning that the balloon

"should not be inflated beyond the 'rated burst pressure' of eight atmospheres," *id.* at 4a. Such proposed state law requirements are specific. They also are different from the design and labeling requirements that FDA imposed in the PMA process. The MDA therefore prevents the state from imposing these proposed requirements, whether by statute, regulation, or common-law.

## II. A FINDING THAT THE PMA PROCESS PREEMPTS STATE PRODUCT LIABILITY CLAIMS WOULD PROMOTE THE PURPOSES OF THE MDA.

The overarching purpose of the Medical Device Amendments is to protect the public health. The MDA's preemption of product liability claims against devices approved through the PMA process serves that objective. A manufacturer facing tort liability for a medical device that has run the PMA gauntlet in theory would have several possible choices. First, the manufacturer could continue to market the device as approved by the FDA in the PMA process and shoulder the costs and burdens of litigation. Because the requirements in the PMA are just that, "requirements," this is usually the only choice for manufacturers, but it is neither a practical nor a tolerable one. The cost of litigation is staggering, particularly in cases involving medical devices, which, like pharmaceutical cases, often involve a "predominance of factual issues – design defect, warning inadequacy, and causation – that generally preclude the resolution of disputes on motion for summary judgment." Note, *A Question of Competence: The Judicial Role in the Regulation of*

*Pharmaceuticals*, 103 Harv. L. Rev. 773, 782 (1990). Losing one significant case is likely to trigger "an avalanche" of others. David E. Bernstein, *The Breast Implant Fiasco*, 87 Cal. L. Rev. 457, 463 (1999). The risk of multiple damage awards, plus the cost and disruption of massive, intrusive, and interminable litigation create a "hydraulic pressure" to settle. *Newton v. Merrill Lynch, Pierce, Fenner & Smith, Inc.*, 259 F.3d 154, 164 (3d Cir. 2001). Whether the companies settle or litigate, the costs are necessarily are reflected in the price of the device – and other products they make. *Cf.* Richard L. Manning, *Products Liability and Prescription Drug Prices in Canada and the United States*, 40 J.L. & Econ. 203, 227 (1997) (finding "a substantial premium exists in the U.S. pharmaceutical prices, strongly related to the prospective costs of litigation, which is absent in Canadian prices"). That would further raise the escalating cost of health care and perhaps limit access to medical technology that FDA has found beneficial to the public health. *See, e.g.*, W. Kip Viscusi, Reforming Products Liability (1991). Congress did not intend that result, and Section 360k cannot be interpreted to permit it.

Petitioner premises her argument on the availability of a second option for a manufacturer – changing the device or its labeling as demanded by the plaintiffs. That alternative, however, would not necessarily avoid liability in the initial cases against the manufacturer or in subsequent cases seeking some different modification. And the manufacturer still would have to pay judgments and bear the burdens of litigation, despite full compliance with FDA requirements. Moreover, FDA might not approve the changes under the PMA supplement

process. *See* 21 C.F.R. § 814.39. If the Agency did not do so, the manufacturer would be unable to fulfill its state law duty while also complying with FDA regulations.

In such a conflict, Congress has stipulated that FDA requirements prevail, for good reason. The judge, the jury, and the plaintiff in an individual case focus only on the particular matter before the court. In litigation, each lawyer's obligation is solely to represent his or her client zealously. The adversary system, whatever its many virtues, is not designed to regulate the field of medical devices in the interest of the public health. It can be counted on even less to do so in any individual case. FDA, not lawyers for individual litigants, has the job of protecting the public health.

Thus, FDA has recognized in the context of prescription drugs that state lawsuits challenging approved labeling "can erode and disrupt the careful and truthful representation of benefits and risks that prescribers need to make appropriate judgments about drug use." Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products ("Preamble"), 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006). In FDA's judgment, "State-law attempts to impose additional warnings lead to labeling that does not accurately portray a product's risks" and threaten "FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs." *Id.* These principles apply with no less force to FDA regulation of medical devices.

Even supposing one jury could provide manufacturers with proper incentives to make their

products safer, would every jury? Manufacturers have been and likely will continue to be subject to multiple suits in varied jurisdictions. If the PMA process does not preempt state product liability suits imposing requirements at odds with the approved PMA, then juries in every state will influence device regulation, in numerous and often conflicting ways. *See, e.g., Brooks v. Howmedica, Inc.*, 273 F.3d 785, 797 (8th Cir. 2001) (en banc) ("[N]ational uniformity in product regulation [is] one of the explicit goals of the MDA."). Inconsistent jury determinations would "create chaos for both the regulated industry and FDA." *Horn v. Thoratec*, 376 F.3d 163, 178 (3d Cir. 2004) (quoting Statement of Interest of the United States, *Murphree v. Pacesetter et al.*, Civ. No. CT-005429-00-3, at 8 (Cir. Ct. Tenn., 13th Jud. Dist., filed Dec. 12, 2003)). Such disarray is the "antithesis of the orderly scheme Congress put in place and charged the FDA with implementing." *Id.* Unless products liability claims such as Petitioner's are preempted, FDA's expert determinations will be supplanted by a myriad of common law regulators, each one less likely than FDA to reach a right result.

Petitioner and her *amici* suggest that supplanting FDA's determinations is salutary because the Agency's regulation is inadequate. That argument, however, is not properly addressed to an Article III court. In fact, Congress recently bolstered FDA's regulation in this area, authorizing additional funding of $39,232,000 over the next five years for post-market surveillance of medical devices. Food and Drug Administration Amendments Act, Pub. L. No. 110-85, 121 Stat. 823 (2007), § 215. No case has intimated that preemption turns on whether the Court thinks the Agency is doing

a good job. But even if the reports Petitioner cites were correct that FDA is understaffed and ineffectual, the solution would not be to allow state tort suits that, by FDA's own assessment, obstruct the Agency in performing its statutorily mandated role. Indeed, nothing in the cited reports suggests that state tort litigation is a solution to FDA's problems. In attempting to supply that missing link and to characterize litigation as an alternative or supplement to FDA regulation, Petitioner and her *amici* seek not only to intrude where FDA has disinvited them, but also to use means that are unsuited for the stated purpose.

A third option for a company facing liability involving an approved medical device is to withdraw it from the market. Depriving patients of medical products that the FDA has found safe and effective does not promote the public health. Yet that may well occur if the Court does not effectuate Congress's intent as expressed in Section 360k of the MDA.

In short, in the circumstances presented here, preemption of state tort claims both advances the public health and enforces congressional intent. Petitioner's argument amounts to a plea that this Court decline to apply the law as written, because doing so may leave some injured patients without the ability to sue, and because the FDA is supposedly ineffective. The argument is addressed to the wrong branch of government.

## CONCLUSION

For the foregoing reasons, the Court should affirm the Court of Appeals judgment that the Medical Device Amendments preempt Petitioner's claims.

Respectfully submitted,

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# APPENDIX

## APPENDIX A — CORPORATE MEMBERS OF THE PRODUCT LIABILITY ADVISORY COUNCIL AS OF 8/6/2007

3M

A.O. Smith Corporation

Altec Industries

Altria Corporate Services, Inc.

American Suzuki Motor Corporation

Andersen Corporation

Anheuser-Busch Companies

Appleton Papers, Inc.

Arai Helmet, Ltd.

Astec Industries

BASF Corporation

Bayer Corporation

Bell Sports

Beretta U.S.A Corp.

BIC Corporation

Biro Manufacturing Company, Inc.

Black & Decker (U.S.) Inc.

BMW of North America, LLC

Boeing Company

Bombardier Recreational Products

BP America Inc.

*Appendix A*

Bridgestone Americas Holding, Inc.

Briggs & Stratton Corporation

Brown-Forman Corporation

CARQUEST Corporation

Caterpillar Inc.

Chevron Corporation

Continental Tire North America, Inc.

Cooper Tire and Rubber Company

Coors Brewing Company

Crown Equipment Corporation

DaimlerChrysler Corporation

The Dow Chemical Company

E & J Gallo Winery

E.I. DuPont De Nemours and Company

Eaton Corporation

Eli Lilly and Company

Emerson Electric Co.

Engineered Controls International, Inc.

Estee Lauder Companies

Exxon Mobil Corporation

Ford Motor Company

Freightliner LLC

*Appendix A*

Genentech, Inc.

General Electric Company

General Motors Corporation

GlaxoSmithKline

The Goodyear Tire & Rubber Company

Great Dane Limited Partnership

Harley-Davidson Motor Company

The Heil Company

Honda North America, Inc.

Hyundai Motor America

Illinois Tool Works, Inc.

International Truck and Engine Corporation

Isuzu Motors America, Inc.

Jarden Corporation

Johnson & Johnson

Johnson Controls, Inc.

Joy Global Inc., Joy Mining Machinery

Kawasaki Motors Corp., U.S.A.

Kia Motors America, Inc.

Koch Industries

Kolcraft Enterprises, Inc.

Komatsu America Corp.

*Appendix A*

Kraft Foods North America, Inc.

Lincoln Electric Company

Magna International Inc.

Mazda (North America), Inc.

Medtronic, Inc.

Merck & Co., Inc.

Michelin North America, Inc.

Microsoft Corporation

Mine Safety Appliances Company

Mitsubishi Motors North America, Inc.

Nintendo of America, Inc.

Niro Inc.

Nissan North America, Inc.

Nokia Inc.

Novartis Consumer Health, Inc.

Novartis Pharmaceuticals Corporation

Occidental Petroleum Corporation

PACCAR Inc.

Panasonic

Pfizer Inc.

Porsche Cars North America, Inc.

PPG Industries, Inc.

*Appendix A*

Purdue Pharma L.P.

Putsch GmbH & Co. KG

The Raymond Corporation

Raytheon Aircraft Company

Remington Arms Company, Inc.

Rheem Manufacturing

RJ Reynolds Tobacco Company

Sanofi-Aventis

Schindler Elevator Corporation

SCM Group USA Inc.

Shell Oil Company

The Sherwin-Williams Company

Smith & Nephew, Inc.

St. Jude Medical, Inc.

Sturm, Ruger & Company, Inc.

Subaru of America, Inc.

Synthes (U.S.A.)

Terex Corporation

Textron, Inc.

TK Holdings Inc.

The Toro Company

Toshiba America Incorporated

Toyota Motor Sales, USA, Inc.

*Appendix A*

TRW Automotive
UST (U.S. Tobacco)
Vermeer Manufacturing Company
The Viking Corporation
Volkswagen of America, Inc.
Volvo Cars of North America, Inc.
Vulcan Materials Company
Watts Water Technologies, Inc.
Whirlpool Corporation
Wyeth
Yamaha Motor Corporation, U.S.A.
Yokohama Tire Corporation
Zimmer, Inc.

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No. 06-179

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In The
# Supreme Court of the United States

CHARLES R. RIEGEL and
DONNA S. RIEGEL,

*Petitioners,*

v.

MEDTRONIC, INC.,

*Respondent.*

**On Writ Of Certiorari To The United States Court Of Appeals For The Second Circuit**

## BRIEF OF THE PUBLIC HEALTH ADVOCACY INSTITUTE, PRESCRIPTION ACCESS LITIGATION LLC, AND COMMUNITY RIGHTS COUNSEL AS *AMICI CURIAE* IN SUPPORT OF PETITIONERS

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## QUESTION PRESENTED

*Amici* address the following question:

Whether an express preemption provision preempts State law claims where the provision fails to contain an unambiguous statement reflecting Congress's intent to include the State law claims within the scope of preemption.

TABLE OF CONTENTS


| | Page |
|---|---|
| TABLE OF AUTHORITIES | iii |
| INTEREST OF THE *AMICI CURIAE* | 1 |
| SUMMARY OF ARGUMENT | 2 |
| ARGUMENT | 4 |
| I. BINDING PRECEDENT REQUIRES AN EXPRESS PREEMPTION PROVISION TO BE CLEAR AND UNAMBIGUOUS AS TO ITS SCOPE AND APPLICATION | 5 |
| II. THE REQUIREMENT THAT EXPRESS PREEMPTION PROVISIONS BE UNAMBIGUOUS RESPECTS THE PROPER ROLE OF THE STATES IN OUR FEDERAL SYSTEM | 9 |
| III. THE REQUIREMENT THAT EXPRESS PREEMPTION PROVISIONS BE UNAMBIGUOUS PROMOTES POLITICAL ACCOUNTABILITY | 13 |
| IV. THE REQUIREMENT THAT EXPRESS PREEMPTION PROVISIONS BE UNAMBIGUOUS PROMOTES PREDICTABILITY IN THE LAW | 16 |
| CONCLUSION | 19 |

# TABLE OF AUTHORITIES

Page

CASES

*Alden v. Maine*, 527 U.S. 706 (1999) ..... 12

*Atascadero State Hosp. v. Scanlon*, 473 U.S. 234 (1985) ..... 8

*Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005) ..... 2, 6, 7, 8

*Bowen v. Georgetown Univ. Hosp.*, 488 U.S. 204 (1988) ..... 18

*Chiarella v. United States*, 445 U.S. 222 (1980) ..... 17

*Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311 (1981) ..... 2, 5, 6

*Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992) .... 7, 8

*Conroy v. Aniskoff*, 507 U.S. 511 (1993) ..... 15

*Egelhoff v. Egelhoff*, 532 U.S. 141 (2001) ..... 4

*Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132 (1963) ..... 2, 6

*Gade v. National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88 (1992) ..... 14

*Gregory v. Ashcroft*, 501 U.S. 452 (1991) ..... 10

*Hines v. Davidowitz*, 312 U.S. 52 (1941) ..... 6

*Landgraf v. USI Film Prods.*, 511 U.S. 244 (1994) ..... 18

*Lane v. Pena*, 518 U.S. 187 (1996) ..... 8

*Library of Cong. v. Shaw*, 478 U.S. 310 (1986) ..... 8

*Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996) ..... 7, 8, 12, 16

*National Ass'n of Home Builders v. Defenders of Wildlife*, 127 S. Ct. 2518 (2007) ..... 17

TABLE OF AUTHORITIES – Continued

Page

*New State Ice Co. v. Liebmann*, 285 U.S. 262 (1932) ..... 10

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*Rapanos v. United States*, 126 S. Ct. 2208 (2006) ..... 14

*Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218 (1947) ..... 5

*Robert C. Herd & Co. v. Krawill Mach. Corp.*, 359 U.S. 297 (1959) ..... 17

*Shaw* v. *Railroad Co.*, 101 U.S. 557 (1880) ..... 17

*Sprietsma v. Mercury Marine*, 537 U.S. 51 (2002) ..... 6, 15

*United States v. Lopez*, 514 U.S. 549 (1995) ..... 11

*Younger v. Harris*, 401 U.S. 37 (1971) ..... 4, 9

STATUTES

Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ..... 4, 5

Medical Device Amendments of 1976, 21 U.S.C. § 360c *et seq.* ..... 4

21 U.S.C. § 360k(a) ..... *passim*

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TABLE OF AUTHORITIES – Continued

Page

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Steven G. Calabresi, *"A Government of Limited and Enumerated Powers": In Defense of* United States v. Lopez, 94 Mich. L. Rev. 752 (1995) ..... 10

MISCELLANEOUS

121 Cong. Rec. 10688 (1975) ..... 15

Exec. Order No. 12612, 52 Fed. Reg. 41685 (Oct. 26, 1987) ..... 11

Exec. Order No. 13132, 64 Fed. Reg. 43255 (Aug. 4, 1999) ..... 12

President George Bush, *Memorandum on Federalism*, 26 Weekly Comp. Pres. Doc. 264 (Feb. 16, 1990) ..... 11

The Federalist No. 10 (C. Rossiter ed. 1961) ..... 13

The Federalist No. 43 (C. Rossiter ed. 1961) ..... 14

The Federalist No. 51 (C. Rossiter ed. 1961) ..... 11

## INTEREST OF THE *AMICI CURIAE*[1]

The Public Health Advocacy Institute is a nonprofit organization founded in 1979 and located at Northeastern University School of Law in Boston. The Institute is devoted to supporting and enhancing public health understanding and commitment among law teachers and students, legislators, regulators, the courts, and others who shape public policy through the law. Its primary area of research and scholarship focuses on legal strategies to reduce the adverse public health impact of tobacco industry products.

Prescription Access Litigation LLC (PAL) is a nonprofit organization that uses litigation and consumer education to challenge illegal pharmaceutical industry tactics. PAL is a coalition of over 130 State, local, and national organizations, including senior citizen groups, consumer advocates, health care advocates, legal services offices, nonprofit health plans, labor unions, and union benefit funds. The members of the PAL coalition have a combined membership of over 13 million individuals. A number of PAL member organizations are plaintiffs in lawsuits regarding drug marketing and advertising that involve preemption issues under the Federal Food, Drug, and Cosmetic Act.

Community Rights Counsel (CRC) is a nonprofit public interest law firm that assists State and local officials and others in defending against constitutional challenges to

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[1] The parties have consented to the filing of this brief, and letters reflecting that consent have been filed with the Clerk. This brief was not authored in whole or in part by counsel for a party, and no person or entity other than *amici*, their members, and their counsel made a monetary contribution to the preparation or submission of this brief.

State and local protections, with a particular emphasis on challenges under the Supremacy Clause and Takings Clause. Since its founding in 1997, CRC has filed *amicus* briefs in preemption cases before this Court in support of many State and local laws. It also has represented scores of governmental and nonprofit organizations in federal and State appellate courts across the country.

*Amici* believe that the public cannot be adequately protected against dangerous medical devices and other products without effective State law tort remedies. *Amici* thus have a strong interest in this case and the development of preemption law generally.

## SUMMARY OF ARGUMENT

There is a presumption against preemption, and that presumption is especially strong where the subject matter at issue implicates the States' historic police power to protect public health and safety. The Court refuses to find preemption of State law unless "the nature of the regulated subject matter permits no other conclusion" or "the Congress has unmistakably so ordained." *Chicago & N.W. Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981) (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963)).

In express preemption cases, the Court implements this strong presumption against preemption by requiring that the preemption provision be "nonambiguous." *Bates v. Dow Agrosciences LLC*, 544 U.S. 431, 449 (2005). The preemptive statement must be pellucidly clear not only as to the *fact* of preemption, but also as to its *scope*, providing unmistakable evidence that the challenged State laws fall

within the boundaries of preemptive act. Express preemption provisions should be narrowly interpreted, and any ambiguities must be construed against preemption, with ties going to the States.

Application of these fundamental interpretive principles in defining the scope of express preemption provisions promotes several values critical to our federal system. Appropriate respect for State sovereignty is essential to the ability of the States to serve as laboratories of experimentation on important issues of public policy. State officials are best positioned to evaluate the diverse conditions across the nation and gauge the needs of the citizenry through appropriately tailored laws and remedies. The requirement that express preemption provisions be unambiguous derives from and enhances this vital role played by the States in our federal system.

Requiring express preemption provisions to be completely clear as to their scope also allows federal officials to be held accountable when they override the voter preferences reflected in State laws, including decisions by State legislatures to retain common law remedies. When special interests persuade federal legislators to abolish widely supported State law protections, the requirement that express preemption provisions be unambiguous helps to ensure that those legislators face the appropriate consequences in subsequent elections.

The interpretive principles that apply to express preemption provisions also promote clarity and predictability in the law. Federal courts should not casually infer congressional intent to preempt longstanding State common law remedies. Just as courts decline to read one statute as repealing another absent a clear mandate, or

refrain from applying a statute retroactively without clear authorization to do so, the requirement that express preemption provisions be unambiguous as to their scope helps to protect settled expectations, enhance predictability, and preserve clarity in the law.

## ARGUMENT

This is a case about federalism. Its proper resolution depends on the application of neutral principles that promote State sovereignty, the role of the States as laboratories of policy experimentation, and other essential elements of "Our Federalism." *Younger v. Harris*, 401 U.S. 37, 44 (1971).

Indeed, preemption cases often provide the best test of the judiciary's commitment to federalist principles. A distinguished federal appellate task force led by then-Judge Kenneth Starr opened its comprehensive report on preemption by emphasizing that "[f]ederal preemption of state law implicates fundamental issues of governmental authority that go to the very heart of our federal system." Kenneth Starr, *et al.*, THE LAW OF PREEMPTION: A REPORT OF THE APPELLATE JUDGES CONFERENCE, 1 (ABA 1991) (hereinafter "STARR REPORT ON PREEMPTION"); *accord Egelhoff v. Egelhoff*, 532 U.S. 141, 160-161 (2001) (Breyer, J., dissenting) ("[T]he true test of federalist principle may lie * * * in those many statutory cases where courts interpret the mass of technical detail that is the ordinary diet of the law."; citations omitted).

The Riegels' opening brief explains why the Medical Device Amendments of 1976 (MDA) to the Federal Food, Drug, and Cosmetic Act, specifically 21 U.S.C. § 360k(a),

does not preempt the State common law claims at issue, and *amici* need not repeat those arguments here. Instead, we address a single, but highly significant, interpretive rule that bears on the question presented, namely the requirement that Congress provide a clear, unambiguous textual description of the scope of preemption in express preemption provisions such as section 360k(a).

Even without this rule, the Riegels should prevail because, as shown in their brief, the best reading of section 360k(a) allows the State law claims to proceed. But if this Court were to conclude that section 360k(a) is ambiguous on the issue, the Riegels still should prevail because that provision does not contain a clear and unambiguous statement that these State law claims are preempted.

## I. BINDING PRECEDENT REQUIRES AN EXPRESS PREEMPTION PROVISION TO BE CLEAR AND UNAMBIGUOUS AS TO ITS SCOPE AND APPLICATION.

There is a strong presumption against preemption, and its pedigree runs deep. For more than eighty years, the Court has stressed that it "start[s] with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947) (citing cases extending back to 1926). The Court uses very demanding language to articulate this strong presumption, insisting that there is no preemption unless "the nature of the regulated subject matter permits no other conclusion" or "Congress has unmistakably so ordained." *Chicago & N.W.*

*Transp. Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981) (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963)).[2]

In express preemption cases,[3] the Court implements this strong presumption against preemption by requiring that the preemption provision be clear as to its scope, and by resolving textual ambiguities against preemption. For example, in *Bates v. Dow Agrosciences LLC*, 544 U.S. 431 (2005), the Court addressed whether an express preemption provision in a federal pesticide statute preempts State common law and statutory tort actions. The Court made clear that any ambiguity in the express preemption provision must be read as cutting against preemption:

> Even if Dow had offered us a plausible alternative reading of § 136v(b) – indeed, even if its alternative reading were just as plausible as our reading of that text – we would nevertheless have a duty to accept the reading that disfavors preemption.

*Id.* at 449. After reciting the presumption against preemption, the *Bates* Court ruled that the express preemption

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[2] Unlike the instant case, the nature of the subject matter might suggest preemption when the challenged State law bears upon peculiarly federal interests, such as foreign policy or immigration. *See Hines v. Davidowitz*, 312 U.S. 52 (1941). There is no peculiarly federal interest at issue here.

[3] This brief addresses only express preemption, but it is worth noting that in cases involving implied preemption, the strong presumption against preemption applies with equal force, and Congress's intent to preempt still must be "clear and manifest." *Sprietsma v. Mercury Marine*, 537 U.S. 51, 69 (2002) (citation omitted). The exacting rules governing the proper reading of express preemption provisions comfortably coexist with the demanding legal standards that govern implied preemption.

provision before it would not apply to State law tort claims absent "a nonambiguous command" in the text of the provision. *Id.* In other words, where there is ambiguity, there is no preemption. And where ambiguity leaves the interpretive enterprise in perfect equipoise – even where the preemptive reading is "just as plausible" as the *Bates* Court put it (*id.*) – ties go to the preservation of State law. The *Bates* Court found it "particularly dubious" that the federal pesticide law contained "a nonambiguous command" to preempt various tort claims at issue there, given that the United States had taken conflicting positions on the matter. *Id.*

In *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), the Court implemented the presumption against preemption by narrowly construing an express preemption provision in the federal law governing cigarette labeling and advertising. As the Court put it, the presumption "reinforces the appropriateness of a narrow reading" of the express preemption provision. *Id.* at 518; *accord id.* at 523 (plurality) ("[W]e must fairly but – in light of the strong presumption against pre-emption – narrowly construe the precise language of §5(b) * * * .").

More significantly, in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), the Court relied on *Cipollone* to support a narrow construction of the very provision at issue here, section 360k(a). *Id.* at 485. The *Medtronic* Court expressly rejected the argument that this presumption, as well as the resulting narrowing construction, do not apply to the scope of an express preemption provision:

> Although dissenting Justices have argued that this assumption should apply only to the question whether Congress intended any pre-emption at all, as opposed to questions concerning the

> *scope* of its intended invalidation of state law, we used a "presumption against the pre-emption of state police power regulations" to support a narrow interpretation of such an express command in *Cipollone*.

*Id.* (emphasis in original; citation omitted).

These interpretive principles requiring complete clarity in express preemption provisions find support not only in *Bates*, *Cipollone*, *Medtronic*, and other preemption cases, but also in rulings imposing analogous clear statement rules designed to promote federalism. For example, out of respect for State sovereignty and State prerogatives, the Court will find congressional abrogation of State sovereign immunity only where the plain text of a federal statute makes the abrogation "unmistakably clear." *Atascadero State Hosp. v. Scanlon*, 473 U.S. 234, 242 (1985); *accord, Lane v. Pena*, 518 U.S. 187, 192 (1996) (waiver "must be unequivocally expressed in the statutory text"); *Library of Congress v. Shaw*, 478 U.S. 310, 318 (1986) (there can by no waiver "by use of ambiguous language"). Like the requirement to avoid ambiguity that applies to express preemption provisions, the clear statement requirement for abrogation of sovereign immunity applies not only to the existence of a waiver, but to its scope as well. *E.g.*, *Lane*, 518 U.S. at 192 (a waiver of sovereign immunity "will be strictly construed, in terms of its scope, in favor of the sovereign").

Of course, no one would argue that the interpretive principles that apply to sovereign immunity are identical in all respects to those that govern preemption cases. One obvious difference is that the Court recognizes implied preemption in limited circumstances, but does not recognize implied immunity waivers. But in express preemption

cases, the jurisprudence that governs immunity waivers provides an especially helpful analogy because it is rooted in the same fundamental principles regarding respect for State sovereignty.

In short, the Congress may not impinge upon State sovereignty or readjust the federal-State balance through an express preemption provision that is ambiguous as to whether the State authority at issue is preempted. Express preemption provisions must be completely clear that the challenged State laws fall within the scope of the provision, with ambiguities resolved against preemption. As the Riegels' brief demonstrates, section 360k(a) does not contain a clear statement that reflects Congress's unmistakable intent to preempt the State common law remedies at issue. Accordingly, there is no preemption.

## II. THE REQUIREMENT THAT EXPRESS PREEMPTION PROVISIONS BE UNAMBIGUOUS RESPECTS THE PROPER ROLE OF THE STATES IN OUR FEDERAL SYSTEM.

The political and policy rationales that underlie "Our Federalism" help to explain why express preemption provisions must be clear and unambiguous regarding their application to a challenged State law.

First, our federal system reflects the fundamental truth that, absent a compelling need for national uniformity, government officials closest to the people are most responsive to their desires. *E.g.*, *Younger v. Harris*, 401 U.S. at 44 (explaining that federalism is not "blind deference to 'States Rights' " but is instead based on "the belief that the National Government will fare best if the States and their institutions are left free to perform their separate

functions in their separate ways."); Steven G. Calabresi, *"A Government of Limited and Enumerated Powers": In Defense of* United States v. Lopez, 94 Mich. L. Rev. 752, 775 (1995) (explaining that federalism improves the quality of government decision-making due to increased information flow and greater efficiency at the State level, and by ensuring policymakers are better informed of the costs and benefits of competing policy options).

Second, State laws often are more effective than a one-size-fits-all national policy because they can be tailored to fit regional and local conditions. *E.g.*, *Gregory v. Ashcroft*, 501 U.S. 452, 458 (1991) ("This federalist structure of joint sovereigns * * * assures a decentralized government that will be more sensitive to the diverse needs of a heterogeneous society."); Michael W. McConnell, *Federalism: Evaluating the Founders' Design*, 54 U. Chi. L. Rev. 1484, 1493 (1987) ("The first, and most axiomatic, advantage of decentralized government is that local laws can be adapted to local conditions and local tastes * * * .").

Third, a diversity of State laws allows the States to act as laboratories of experimentation on important issues of public policy. The classic statement of this advantage appears in Justice Brandeis's dissent in *New State Ice Co. v. Liebmann*, 285 U.S. 262 (1932): "It is one of the happy incidents of the federal system that a single courageous State may, if its citizens choose, serve as a laboratory; and try novel social and economic experiments without risk to the rest of the country." *Id.* at 311; *accord*, *Gregory v. Ashcroft*, 501 U.S. at 458 (federalism "allows for more innovation and experimentation in government"). Indeed, State sovereigns often have powerful incentives to find the best public policies in order to attract additional taxpayers, thereby fostering a healthy competition among the

States as the citizenry votes with its feet. *See* McConnell, *Federalism: Evaluating the Founders' Design*, 54 U. Chi. L. Rev. at 1498-1500.

Fourth, a proper federal-State balance helps to enhance liberty by ensuring that each level of government checks the abuses of the other. As Justice Kennedy put it: "Though on the surface the idea may seem counterintuitive, it was the insight of the Framers that freedom was enhanced by the creation of two governments, not one." *United States v. Lopez*, 514 U.S. 549, 576 (1995) (Kennedy, J., concurring); *accord*, *Printz v. United States*, 521 U.S. 898, 920 (1997) (same, quoting Justice Kennedy); The Federalist No. 51, p. 323 (C. Rossiter ed. 1961) (describing this "double security"). A casual override of State prerogatives by the federal judiciary in express preemption cases would severely threaten the federal-State balance vital to this double protection of liberty.

These and other fundamental principles that underlie "Our Federalism" transcend partisan divisions. In the original Executive Order on Federalism, President Ronald Reagan emphasized that "[t]he nature of our constitutional system encourages a healthy diversity in the public policies adopted by the people of the several States according to their own conditions, needs, and desires." Exec. Order No. 12612, 52 Fed. Reg. 41685, § 2(f) (Oct. 26, 1987) (prohibiting agencies from adopting uniform national standards to the maximum extent possible); *see also* President George Bush, *Memorandum on Federalism*, 26 Weekly Comp. Pres. Doc. 264 (Feb. 16, 1990) (reaffirming President Reagan's executive order on federalism).

Similarly, President Clinton's Executive Order on Federalism stressed that "[f]ederalism is rooted in the

belief that issues that are not national in scope or significance are most appropriately addressed by the level of government closest to the people." Exec. Order No. 13132, 64 Fed. Reg. 43255, § 2(a) (Aug. 4, 1999). The order recognized that "States possess unique authorities, qualities, and abilities to meet the needs of the people and should function as laboratories of democracy." *Id.* (section 2(e)). And it sought to promote "a healthy diversity in the public policies adopted by the people of the several States" because "one-size-fits-all approaches to public policy problems can inhibit the creation of effective solutions to those problems." *Id.* (section 2(f)).

In addition to these pragmatic and policy advantages, the requirement that an express preemption provision be unmistakably clear as to its scope also derives from the simple dignity of the States as sovereign entities. As the Court put it in *Alden v. Maine*, 527 U.S. 706 (1999), the States should not be "relegated to the role of mere provinces or political corporations, but retain the dignity, though not the full authority, of sovereignty." *Id.* at 715. The Congress and the federal judiciary would be doing severe violence to sovereign dignity if an ambiguous preemption provision were sufficient to trump the long-standing laws of the sovereign States. *See Medtronic*, 518 U.S. at 488 (declining to find preemption of State common law remedies under the MDA in part because preemption would constitute "serious intrusion into state sovereignty."); Betsy J. Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B. U. L. Rev. 559, 627 (1997) ("[R]equiring that Congress speak clearly will help ensure that its decision to preempt is the

product of a deliberate policy choice. Our system of federalism demands that interference with states' policy decisions to give their citizens tort remedies should be the product of judgment and careful balancing, rather than an unintended result of congressional inattention or imprecision.").

## III. THE REQUIREMENT THAT EXPRESS PREEMPTION PROVISIONS BE UNAMBIGUOUS PROMOTES POLITICAL ACCOUNTABILITY.

Requiring express preemption provisions to be clear and unambiguous as to their scope also enhances democratic values by preserving political accountability. It is not uncommon for a majority of citizens to hold a position on an important matter of public policy that is at odds with the position of special interests or factions. *See* The Federalist No. 10, pp. 77-84 (C. Rossiter ed. 1961) (discussing the "mischief of faction"). One could easily imagine a situation in which a vast majority of the voting public prefers that the U.S. Congress refrain from abolishing State damage remedies, but special interests favor abolition and lobby heavily to obtain it. Without a requirement for clarity in express preemption provisions, federal legislators might be tempted to enact an ambiguous provision with the hope that the courts would resolve the ambiguity in favor of preemption, thereby satisfying the special interests while maintaining plausible deniability with their constituents.

Requiring clarity in express preemption provisions prevents federal politicians from side-stepping the political accountability that lies at the heart of our democracy. The Founders emphasized that "the residuary sovereignty of

the States [is] implied and secured by that principle of representation in one branch of the [federal] legislature." The Federalist No. 43, p. 279 (C. Rossiter ed. 1961). In other words, the political checks exercised by voters on elected officials are a primary protector of federalism and the federal-State balance. *See* STARR REPORT ON PREEMPTION, at 50.

Judicial reliance on ambiguities to find preemption would improperly curtail State sovereignty and impose a uniform national policy even in the face of the contrary preferences of the citizenry. If our federal representatives truly want to repeal time-honored common law remedies for corporate malfeasance, let them say so clearly and directly, and then face the political consequences.

Moreover, if ambiguous preemption provisions were sufficient to preempt, unelected federal judges might be tempted to resolve ambiguities by resorting to far less reliable indicators of congressional intent, such as perceived statutory "purposes" or "goals." Most statutes, however, come into existence through the legislative resolution of competing purposes and goals. *E.g., Pension Benefit Guar. Corp. v. LTV Corp.*, 496 U.S. 633, 646 (1990) ("[T]here are numerous federal statutes that could be said to embody countless policies."). When the legislative resolution of competing goals is ambiguous with respect to the infringement of State sovereignty, the unelected judiciary is singularly ill-equipped to strike an appropriate balance itself. *Cf. Rapanos v. United States*, 126 S. Ct. 2208, 2234 (2006) (plurality) (cautioning against the practice of "substituting the purpose of the statute for its text"); *Gade v. National Solid Wastes Mgmt. Ass'n*, 505 U.S. 88, 112 (1992) (Kennedy, J., concurring in part and

concurring in the judgment) ("A freewheeling judicial inquiry into whether a state statute is in tension with federal objectives would undercut the principle that it is the Congress rather than the courts that pre-empts state law."); STARR REPORT ON PREEMPTION, at 36 (criticizing the "purpose inquiry" in preemption cases because "a complex of competing legislative policies can be undermined").

For example, in the case at bar, Medtronic might argue that failure to preempt would be inconsistent with a purported "purpose" to promote design innovation. But in enacting the MDA, Congress primarily sought to ensure fully adequate protection of the consumer, "who pays with his health and his life for medical device malfunctions." 121 Cong. Rec. 10688 (1975); *cf.*, *Sprietsma*, 537 U.S. at 64 (2002) (explaining why Congress would preempt State positive law but not State common law to preserve remedies needed to compensate victims). Courts are institutionally ill-positioned to untangle the countless compromises made during the legislative process in an effort to resolve ambiguities in a preemption provision.

In the same way, requiring express preemption provisions to be unambiguous as to their scope avoids the need to resort to legislative history. It is all too easy to scan legislative history as one might look over a "crowd at a party," seeking out only that which is congenial, ignoring that which is unhelpful or unfamiliar. *See Conroy v. Aniskoff*, 507 U.S. 511, 519 (1993) (Scalia, J., concurring in the judgment) (attributing the metaphor to Judge Harold Leventhal). While the risks inherent in legislative history might be unavoidable in other cases involving ambiguous statutes, those risks should not be embraced in order to resuscitate an ambiguous preemption provision that cuts

deeply into State sovereign prerogatives. Requiring textual clarity promotes a more principled approach, one in keeping with the relative institutional capacities of the legislative and judicial branches, and one that affords proper respect to sovereign States.

Nor does the requirement to be unambiguous impose an undue burden on the legislature. The Congress knows full well how to preempt State law tort remedies through a clear textual statement. It easily could have drafted section 360k(a) to include a clear statement preempting all State tort remedies as applied to medical devices. It declined to do so. Instead, section 360k(a) preempts only State and local "requirements," which the *Medtronic* plurality described as "a singularly odd word" to use to refer to common law claims. *Medtronic*, 518 U.S. at 487. Nor did the Congress choose to preempt all such requirements for any given device, but only those requirements that are "different from, or in addition to, any requirement" issued under the MDA to govern the device. This language hardly qualifies as an unambiguous preemption of State common law claims based on general theories of liability that are in no meaningful way a counterpart to any device-specific federal requirement.

## IV. THE REQUIREMENT THAT EXPRESS PREEMPTION PROVISIONS BE UNAMBIGUOUS PROMOTES PREDICTABILITY IN THE LAW.

As the court well knows, the general application of clear statement rules in statutory interpretation promotes greater certainty and stability in the law. In the U.S. Appellate Judges Conference Report on Preemption, Judge Starr and his colleagues supported the vigorous application of a clear statement rule in preemption cases for

several reasons, including enhanced clarity and predictability. STARR REPORT ON PREEMPTION, at 50-53. The Report draws helpful analogies to several other clear statement rules the courts use to interpret statutes to enhance clarity and predictability. *Id.*

For example, courts refuse to read a statute as repealing another statute unless the repeal is expressed in clear language. *E.g.*, *National Ass'n of Home Builders v. Defenders of Wildlife*, 127 S. Ct. 2518, 2532 (2007) (reaffirming that "'repeals by implication are not favored' and will not be presumed unless the 'intention of the legislature to repeal [is] clear and manifest.'"; citation omitted). Courts should read a statute as repealing another statute only where the former "expressly contradicts" the latter or where the reading "is absolutely necessary." *Id.* (quoting and discussing authorities). Just as this clear statement rule protects settled expectations derived from reasonable reliance on existing laws, the requirement that preemption provisions be unambiguous insulates reasonable expectations and settled reliance on established State law from undue judicial interference.

Similarly, statutes in derogation of the common law generally "must be strictly construed." *Robert C. Herd & Co. v. Krawill Mach. Corp.*, 359 U.S. 297, 304 (1959); *accord, Shaw* v. *Railroad Co.*, 101 U.S. 557, 565 (1880) (a statute "is not to be construed as making any innovation upon the common law which it does not fairly express."). Nor should statutes be read to expand well-established common law duties "absent some explicit evidence of congressional intent." *Chiarella v. United States*, 445 U.S. 222, 233 (1980). These clear statement rules shield settled expectations and reliance on the common law from judicial

invalidation absent a clear legislative command. In the same way, courts should not construe a preemption provision to overturn State common law remedies absent an unmistakably clear congressional mandate to do so.

The Court also has made clear it will not read statutes to apply retroactively absent clear instructions in the statutory text. *E.g.*, *Landgraf* v. *USI Film Prods.*, 511 U.S. 244, 264-265 (1994) ("'[C]ongressional enactments * * * will not be construed to have retroactive effect unless their language requires this result.' * * * [T]he presumption against retroactive legislation is deeply rooted in our jurisprudence, and embodies a legal doctrine centuries older than our Republic."; quoting *Bowen* v. *Georgetown Univ. Hosp.*, 488 U.S. 204, 208 (1988)). The reason, of course is that "settled expectations should not be lightly disrupted." *Landgraf*, 511 U.S. at 265. Likewise, settled expectations based on longstanding State laws and protections should not be disrupted without a clear textual statement from Congress requiring this result.

As one scholar put it, "[p]articularly when it legislates in an area affected by state tort law, Congress has much to gain by making explicit its intent to preempt state law. Namely, clarity achieves certainty in statutory application and helps to avoid litigation over legislative meaning." Grey, *Make Congress Speak Clearly: Federal Preemption of State Tort Remedies*, 77 B. U. L. Rev. at 627.

## CONCLUSION

Because section 360k(a) lacks a clear statement preempting the State common law remedies at issue, the judgment of the court of appeals should be reversed.

Respectfully submitted.

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No. 06-179

IN THE

# Supreme Court of the United States

DONNA RIEGEL, individually and as administrator of the ESTATE OF CHARLES R. RIEGEL,
*Petitioner,*

v.

MEDTRONIC, INC.,
*Respondent.*

**On Writ of Certiorari to the United States Court of Appeals for the Second Circuit**

## BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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## QUESTION PRESENTED

Whether the Medical Device Amendments to the federal Food, Drug, and Cosmetic Act preempt state-law products liability claims challenging the design, manufacturing, and labeling of medical devices that the Food and Drug Administration has found to be safe and effective pursuant to its rigorous Premarket Approval process.

## TABLE OF CONTENTS

Page

TABLE OF AUTHORITIES ..... iv

INTERESTS OF THE *AMICI CURIAE* ..... 1

STATEMENT OF THE CASE ..... 2

SUMMARY OF ARGUMENT ..... 6

ARGUMENT ..... 9

I. PETITIONERS' DESIGN DEFECT AND FAILURE-TO-WARN CLAIMS ARE PREEMPTED BY § 360k(a) ..... 9

A. The Language of § 360k(a) Has Been Interpreted in Lohr and Other Cases As Evidence of a Congressional Intent to Preempt Common Law Causes of Action ..... 10

B. Section § 360k(a) Does Not Exclude State Rules of General Applicability from Being Classified as "Requirement[s]" ..... 13

C. States Undermine the Objectives of the MDA When They Second-Guess an FDA Decision to Approve Marketing of Life-Saving Medical Devices Pursuant to FDA-Mandated Design and Labeling Requirements ..... 14

II. PETITIONERS' DESIGN DEFECT AND FAILURE-TO-WARN CLAIMS ARE IMPLIEDLY PREEMPTED BY THE MDA ..... 15

**Page**

A. Implied Preemption Is Fairly Encompassed Within the Question Presented ..... 16

B. The Court Has Regularly Inferred Congressional Intent to Preempt State Laws That Conflict with Federal Law ..... 17

C. Recovery Under the Riegels' Causes of Action Is Preempted Because It Would Undermine the PMA Process Established by Congress ..... 18

D. The Existence of an Express Preemption Provision in the MDA Does Not Preclude an Implied Preemption Finding ..... 23

CONCLUSION ..... 24

## TABLE OF AUTHORITIES

**Page(s)**

**Cases:**

*Barnett Bank of Marion County, N.A. v. Nelson*,
517 U.S. 25 (1996) ..... 17
*Bates v. Dow AgroSciences LLC*,
544 U.S. 431 (2005) ..... 7, 11, 12
*Buckman v. Plaintiffs' Legal Comm.*,
531 U.S. 341 (2001) ..... *passim*
*Cipollone v. Liggett Group, Inc.*,
505 U.S. 504 (1992) ..... 7, 11
*Florida Lime and Avocado Growers, Inc. v. Paul*,
373 U.S. 132 (1963) ..... 18
*Freightliner Corp. v. Myrick*,
514 U.S. 280 (1995) ..... 17
*Geier v. American Honda Motor Co.*,
529 U.S. 861 (2000) ..... 19, 23
*Hines v. Davidowitz*,
312 U.S. 52 (1941) ..... 2, 18
*Jones v. Rath Packing Co.*,
430 U.S. 519 (1977) ..... 17
*Lebron v. Nat'l Railroad Passenger Corp.*,
513 U.S. 374 (1995) ..... 16
*Medtronic, Inc. v. Lohr*,
518 U.S. 470 (1996) ..... *passim*
*Rice v. Santa Fe Elevator Corp.*,
331 U.S. 218, 230 (1947) ..... 17
*Wisconsin Public Intervenor v. Mortier*,
501 U.S. 597 (1991) ..... 17, 18
*Yee v. Escondido*,
503 U.S. 519 (1992) ..... 16

**Page(s)**

**Statutory and Regulatory Provisions:**

Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.* ..... 8

Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539 (1976)(chiefly codified at 21 U.S.C. § 360c *et seq.*) ..... *passim*

Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) ..... 11, 12
7 U.S.C. § 136y(b) ..... 11

National Traffic and Motor Safety Act of 1966, 15 U.S.C. § 1381 *et seq.* ..... 20, 23

21 U.S.C. § 360e(e) ..... 14
21 U.S.C. § 360h(e) ..... 14
21 U.S.C. § 360k(a) ..... *passim*
21 U.S.C. § 360k(a)(1) ..... 4

21 C.F.R. § 814.20 ..... 19
21 C.F.R. § 814.44 ..... 19
21 C.F.R. § 814.80 ..... 19

**Page(s)**

**Miscellaneous:**

FDA, *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) ..... 21

Public Health Advisory, FDA, Worsening Depression and Suicidality in Patients Being Treated With Antidepressant (Mar. 22, 2004), *available at* http://www.fda.gov/cder/drug/antidepressants/AntidepressanstPHA.htm. ..... 22

Robert D. Gibbons, Ph.D. et al., *Early Evidence on the Effects of Regulators' Suicidality Warnings on SSRI Prescriptions and Suicide in Children and Adolescents*, 164 Am. J. Psychiatry 1356, 1358-1359 (2007) ..... 22

Anne M. Libby, Ph.D. et al., *Decline in Treatment of Pediatric Depression After FDA Advisory on Risk of Suicidality With SSRIs*, 164 Am. J. Psychiatry 884, 887 (2007) ..... 22

H.R. Rep. No. 853, 94th Cong., 2d Sess. 9 (1976), *reprinted in* Daniel F. O'Keefe, Jr. & Robert A. Spiegel, *An Analytical Legislative History of the Medical Device Amendments of 1976*, App. III (1976) ..... 15

## BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* IN SUPPORT OF RESPONDENT

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### INTERESTS OF *AMICUS CURIAE*

The Washington Legal Foundation (WLF) is a non-profit public interest law and policy center with supporters in all 50 States.[1] WLF devotes a substantial portion of its resources to defending free-enterprise, individual rights, and a limited and accountable government. To that end, WLF has frequently appeared as *amicus curiae* in this and other federal courts in cases involving preemption issues, to point out the economic inefficiencies often created when multiple layers of government seek simultaneously to regulate the same business activity. *See, e.g., Bates v. Dow AgroSciences LLC,* 544 U.S. 431 (2005); *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001); *Geier v. American Honda Motor Co.*, 529 U.S. 861 (2000); *United States v. Locke,* 529 U.S. 89 (2000).

WLF is particularly concerned that individual freedom and the American economy both suffer when state law, including state tort law, imposes upon industry an unnecessary layer of regulation that frustrates the objectives or operation of specific federal regulatory regimes, such as (in this case) the Medical Device Amendments (MDA).

At issue here is whether Congress intended to preempt Petitioners' causes of action. WLF agrees with Respondents and the U.S. Court of Appeals for the Second Circuit that Congress's preemptive intent under the facts of this case is manifested by the MDA's express preemption provision, 21

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[1] Pursuant to Supreme Court Rule 37.6, WLF states that no counsel for a party authored this brief in whole or in part; and that no person or entity, other than WLF and its counsel, contributed monetarily to the preparation and submission of this brief.

U.S.C. § 360k(a). Quite apart from that provision, however, WLF submits that the MDA impliedly preempts Petitioner's causes of action, because the common law rules Petitioner espouses "stand[] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

WLF has no direct interest, financial or otherwise, in the outcome of this case. It is filing due solely to its interest in the important preemption issues raised by this case. WLF is filing this brief with the consent of both parties, who have filed blanket letters of consent with the Clerk of the Court.

## STATEMENT OF THE CASE

This case involves a state-law personal injury suit filed by Charles Riegel, a New York resident who claimed to have suffered injury during heart surgery involving use of the Evergreen Balloon Catheter, a medical device that was manufactured by Respondent Medtronic, Inc. and entered the market pursuant to the Food and Drug Administration's (FDA) rigorous premarket approval (PMA) process.[2] The suit alleged five common law causes of action: (1) negligence in the design, testing, inspection, manufacture, distribution, labeling, marketing, and sale of the Evergreen Balloon Catheter; (2) strict liability in tort; (3) breach of express warranty; (4) breach of implied warranty; and (5) loss of consortium. Pet. App. 4a-5a.

At issue here is whether federal law preempts certain of those causes of action. The district court held that several of

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[2] His wife, Donna Riegel, also sued for loss of consortium. Following his death, the Court granted Donna's motion to be substituted for Charles (in her capacity as administrator of the estate) as a party to these proceedings.

the causes of action – those involving strict liability, breach of implied warranty, and all of the negligence claims except for the negligent manufacturing claim – were preempted by the Medical Device Amendments of 1976 (MDA), Pub. L. No. 94-295, 90 Stat. 539 (1976) (chiefly codified at 21 U.S.C. § 360c *et seq.*). The district court based its preemption finding on the MDA's express preemption provision, 21 U.S.C. § 360k(a). Pet. App. 5a. Following discovery, the district court granted summary judgment to Medtronic on the remaining claims. *Id.* It dismissed the express warranty claim because Medtronic had clearly disclaimed any express warranty, and it dismissed the negligent manufacturing claim on the grounds that there was insufficient evidence that the Evergreen Balloon Catheter had burst because of negligent manufacture. *Id.*

The Second Circuit affirmed. *Id.* at 1a-54a. The court based much of its legal analysis on this Court's decision in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), which held that § 360k(a) does not preempt state law tort claims filed against manufacturers of Class III medical devices that reach the market by means of the § 510(k) process.[3] The appeals court noted that while devices that can meet the § 510(k) eligibility criteria can gain market access after minimal FDA review, the PMA review process (required for all Class III devices – such as the Evergreen Balloon Catheter – that do not qualify for § 510(k) process) is far more "lengthy and rigorous." Pet. App. 8a. The court also noted that only about 1% of new

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[3] The "§ 510(k) process" (also known as the "premarket notification" process) is the name generally given to the process that allows medical devices to reach the market based on a showing that they are "substantially equivalent" to medical devices that were already being marketed at the time of the MDA's adoption in 1976. *Lohr*, 518 U.S. at 478. The MDA also included a "grandfathering" provision that allowed such pre-1976 devices to remain on the market at least temporarily following adoption of the MDA. *Id.*

medical devices reach the market via PMA review and approval. *Id.* at 13a. The court said that the § 510(k) process "differs dramatically from the PMA process." *Id.* The court explained that while the latter involves an intense FDA review of the device and results in PMA "approval" of the specific device design only if FDA determines that that design provides "reasonable assurance" of safety and effectiveness, the § 510(k) process "'does not in any way denote FDA approval of the device,'" but rather simply signifies that the device is *as safe and effective* as grandfathered medical devices (which were never themselves reviewed for safety and effectiveness. *Id.* at 13a-14a (quoting 21 C.F.R. § 807.97).

The appeals court concluded that the "dramatic[]" difference in the two market-entry methods made a decisive difference under the MDA's express preemption provision, § 360k(a).[4] The court determined that because FDA intensely reviews and actually approves the design and labeling of PMA devices, FDA's approval of the specific design and labeling of the Evergreen Balloon Catheter qualified as a "requirement applicable under this Act to the device," within the meaning of § 360k(a)(1). *Id.* at 25a-29a. The court also concluded that "the Riegels' claims would, if successful, result in state 'requirements' [within the meaning of § 360k(a)] that differed

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[4] Section 360k(a) provides in relevant part:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement –
>
> > (1) which is different from, or in addition to, any requirement applicable under this Act to the device, and
> >
> > (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this Act.

from or added to [the] standards" specified in Medtronic's approved PMA application. *Id.* at 30a.

In finding that the Riegels' design and labeling claims were expressly preempted by § 360k(a), the appeals court deemed the claims to present a direct conflict with the federal PMA approval scheme:

> Yet the Riegels' claims would premise liability on Medtronic's failure to have done something with the Evergreen Balloon Cath[et]er other than adhere to the PMA-approved standards. [¶ ] In fact, it is unclear what a manufacturer of a PMA-approved device would do when faced with a jury verdict on a plaintiff's common law claims, given that the manufacturer would nonetheless be unable to make any modifications affecting the device's safety and effectiveness without obtaining further FDA approval. Moreover, it is certainly conceivable that different juries would reach conflicting verdicts about the same medical devices, thus rendering it almost impossible for a device to comply simultaneously with its federal PMA (which, after all, can only change after an extensive process) and with the various verdicts issued by different juries around the country.

*Id.* 33a-34a.

The appeals court agreed with the district court that the Riegels' negligent manufacturing claim was not preempted, to the extent that it rested on the allegation that the particular Evergreen Balloon Catheter that was deployed during Mr. Riegel's surgery had not been manufactured in accordance with the PMA-approved standards. The court explained, "A jury verdict in the Riegels' favor would not have imposed state requirements that differed from, or added to, the PMA-

approved standards for this device, but would instead have simply sought recovery for Medtronic's alleged deviation from those standards." *Id.* 35a-36. The court went on to uphold the district court's grant of summary judgment to Medtronic on the negligent manufacturing claim, finding that the Riegels had submitted no competent evidence to challenge Medtronic's explanation regarding why the catheter had burst. *Id.* 38a-43a.[5]

In dissent, Judge Pooler would have held that Congress, in adopting § 360k(a), did not intend to include common law tort actions within the category of state "requirement[s]" subject to preemption. *Id.* at 45a-54a.

## SUMMARY OF ARGUMENT

WLF fully agrees with Medtronic's contention that Congress intended to preempt the state-law tort actions at issue in this case. That intent is apparent from the language of the MDA's express preemption provision, 21 U.S.C. § 360k(a). But that intent can *also* be inferred from the overall structure of the MDA; that structure establishes a federal system for determining when new, Class III medical devices are sufficiently safe and effective to be marketed on a nationwide basis in accordance with an FDA-mandated design and labeling. The Riegels' causes of action conflict with that system by asking state courts to determine that the FDA-mandated design and labeling are deficient.

Medtronic has explained at length why § 360k(a) demonstrates Congress's intent to preempt the Riegels' causes of action. WLF will not repeat all of those arguments here.

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[5] Petitioner did not seek review of that portion of the appeals court's ruling, and thus issues related to negligent manufacturing are not now before the Court.

Rather, we wish to emphasize three points regarding that statutory provision. First, Petitioner's assertion that § 360k(a) was never intended to apply to common law actions not only is inconsistent with the views of five of the nine Justices in *Lohr*, but also is inconsistent with other decisions of this Court that have interpreted similarly worded express preemption provisions as applying to common law causes of action. *See Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992). Second, § 360k(a) applies broadly to "any" requirement that is imposed by a State and meets the other criteria established by the statute. Accordingly, there is no statutory basis for Petitioner's assertion that those common law duties that can be said to apply generally to all product manufacturers rather than focusing on specific medical devices are not state "requirement[s]" subject to § 360k(a) preemption. Third, the appeals court decision does not, as Petitioner argues, deprive patients of a remedy for injuries caused by defective medical devices. When it approves a PMA application for a medical device, FDA thereby determines that a medical device designed, manufactured, and labeled in accordance with the FDA-mandated specifications *is not defective*. Thus, by limiting a patient's litigation options, all the MDA is doing is preventing the patient from suing the manufacturer of a non-defective device. Until such time as FDA reverses a decision approving a device's design and labeling, § 360k(a) prohibits States from arriving at a contrary decision by applying a different set of requirements to the device.

In addition to the express preemption arguments articulated by Medtronic, the appeals court decision can be sustained based on an implied preemption argument. Implied preemption is fairly encompassed within the Question Presented, which focuses on whether Congress intended to preempt Petitioner's causes of action. Once the preemption *claim* has been raised, the parties and the Court are free to

address any *arguments* relevant to that issue, regardless whether those specific arguments were raised or passed on in the courts below.

Among the circumstances under which Congress is deemed to have impliedly preempted state law is when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. The Riegels' causes of action are preempted for precisely that reason: recovery under those causes of action would undermine the PMA process established by Congress, by second-guessing FDA determinations that approved products are not defective when marketed in accordance with the FDA-approved labeling and design specifications.

In *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Court held that federal law preempted state-law claims that a medical device manufacturer made fraudulent misrepresentations to FDA for the purpose of obtaining FDA approval for its device. The Court unanimously held that Congress had impliedly intended to preempt such fraud-on-the-FDA claims when it adopted the MDA and the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 301 *et seq.*, because adjudication of such claims would conflict with the FDA product-approval process. *Buckman*, 531 U.S. at 348. Similarly, permitting the Riegels and other injured plaintiffs to bring state-law suits alleging that a PMA medical device is defectively designed or improperly labeled would undermine FDA requirements mandating that the device be designed and labeled in that precise manner.

Such suits cannot be defended based on an argument that federal design and labeling requirements serve merely as a floor and that states are permitted to impose more exacting safety requirements. FDA specifies precise design specifications for a medical device based on a detailed

assessment that the prescribed design is safe and effective. Congress cannot have intended to permit a state-court jury to second-guess such design decisions, where the practical effect would be to require a manufacturer to adopt a different design – one that FDA might well decide is neither safe nor effective. Similarly, FDA imposes labeling requirements based on its considered determination regarding the proper mix of contraindications and warnings. FDA regularly directs manufacturers to limit the strength of warnings included on a label, to avoid scaring away consumers who would benefit from using the product. Yet, if Petitioner were to prevail on her failure-to-warn claim, New York would in effect be requiring Medtronic to alter the labeling mandated by FDA. Under such circumstances, Congress is deemed to have impliedly preempted such common law suits.

The fact that the MDA includes an express preemption provision does not preclude a finding of implied preemption. The Court has on several occasions held that a common law cause of action is impliedly preempted by federal law even though the federal statute at issue contained an express preemption provision. Indeed, although the *Lohr* plurality was skeptical that § 360k(a) should ever operate to preempt a common law cause of action, those same four Justices were more receptive to the idea that the MDA might impliedly preempt some common law causes of action based on conflict preemption. *Lohr*, 518 U.S. at 503 (plurality opinion).

## ARGUMENT

### I. PETITIONERS' DESIGN DEFECT AND FAILURE-TO-WARN CLAIMS ARE PREEMPTED BY § 360k(a)

Section 360k(a) contains four principal elements. To establish preemption under § 360k(a), one must demonstrate:

- a state "requirement";
- a federal "requirement applicable . . . to the device" under the FDCA;
- that the state "requirement" is "different from, or in addition to" the federal "requirement applicable . . . to the device" under the FDCA; and
- that the state "requirement" "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device" under the FDCA.

Medtronic has explained at length in its brief why the Second Circuit was correct in concluding that Medtronic had met each of those four elements. WLF fully concurs in those arguments and will not repeat them here. Rather, we wish to focus on three points that help to explain why the Riegels' common law causes of action do, in fact, constitute state "requirements" within the meaning of § 360k(a).

### A. The Language of § 360k(a) Has Been Interpreted in Lohr and Other Cases As Evidence of a Congressional Intent to Preempt Common Law Causes of Action

Petitioners assert that § 360k(a) was never intended by Congress to apply to common law causes of action. That assertion flies in the face of several decisions of this Court in which the Court stated that both § 360k(a) and similarly worded express preemption statutes did, indeed, apply to common law causes of action.

Although *Lohr* ultimately determined that the common law causes of action at issue in that case were not preempted,

five of the nine Justices stated that such causes of action against medical device manufacturers can and often do constitute state "requirement[s]" within the meaning § 360k(a). *See Lohr*, 518 U.S. at 511-14 (O'Connor, J., concurring in part and dissenting in part) (joined by Chief Justice Rehnquist and Justices Scalia, and Thomas); *id.* at 504 (Breyer, J., concurring in part and concurring in the judgment) ("One can reasonably read the word 'requirement' as including the legal requirements that grow out of the application, in particular circumstances, of a State's tort law."). Justice Breyer drew support for that conclusion from the Court's previous decision in *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504 (1992), stating that *Cipollone* "made clear that similar language [*i.e.*, preemptive language similar to that contained in § 360k(a)] 'easily' encompassed tort actions because '[state] regulation can be as effectively asserted through an award of damages as through some form of preventive relief.'" *Lohr*, 518 U.S. at 504 (quoting *Cipollone*, 505 U.S. at 521). Similarly, in *Bates v. Dow AgroSciences LLC*, 544 U.S. 431 (2005), the Court held that 7 U.S.C. § 136y(b) – the express preemption provision of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), a provision that includes "any requirement" language similar to the language in § 360k(a) – operated to preempt common law causes of action.[6]

Petitioner's efforts to rewrite *Bates* are without merit. Asserting that a common law court judgment cannot constitute a state "requirement" within the meaning of § 360k(a), she cites *Bates* for the proposition that "'an event, such as a jury verdict, that merely motivates an optional decision is not a requirement.'" Pet. Br. 12 (quoting *Bates*, 544 U.S. at 445). When read in context, the quoted language from *Bates* strongly

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[6] Section 136y(b) provides that States "shall not impose or continue in effect any requirement for labeling or packaging in addition to or different from those required under this subchapter."

supports Medtronic. The quoted language appears in a section of the opinion that discusses when a common law judgment should be deemed a preempted "requirement" for labeling or packaging within the meaning of FIFRA. The lower court had ruled that the FIFRA preemption provision operates to preempt common law causes of action *whenever* a finding of liability on those claims would "induce" a manufacturer to alter its product label. The Court rejected that approach, stating, "This effects-based test finds no support in the text of [the FIFRA preemption provision], which speaks only of 'requirements.'" *Id.* Rather, the Court explained:

> A requirement is a rule of law that must be obeyed; an event, such as a jury verdict, that merely motivates an optional decision is not a requirement. The proper inquiry calls for an examination of the elements of the common law duty at issue.

*Id.* (citing *Cipollone,* 505 U.S. at 524). The Court said that a design defect claim should not be deemed a "requirement" regarding "labeling or packaging" merely because, if successful, it would "induce a manufacturer to alter its label to reflect a change in the list of ingredients or a change in the instructions for use necessitated by the improvement in the product's design." *Id.* at 445-46. Under the examine-the-elements-of-the-duty approach endorsed by *Bates*, the Court determined that the petitioners' fraud and negligent-failure-to-warn claims were premised on common law rules that *did* qualify as "requirements for labeling or packaging" because they "set a standard for a product's labeling that the [defendant's] label [wa]s alleged to have violated by containing false statements and inadequate warnings. *Id.* at 446.

Similarly, the Riegels' causes of action, if successful, unquestionably would constitute "requirement[s]" within the

meaning of § 360k(a). A design defect and failure-to-warn judgment in Petitioner's favor would require Medtronic to alter the FDA-mandated design and labeling of its product.

### B. Section § 360k(a) Does Not Exclude State Rules of General Applicability from Being Classified as "Requirement[s]"

Section 360k(a) broadly preempts "any" state requirement that meets the other criteria established for preemption. Petitioner nonetheless insists that state rules of general applicability – a category that includes virtually all common law tort rules – do not fall within § 360k(a)'s definition of a state "requirement" and thus are never subject to preemption. Pet. Br. 34-39.

WLF notes initially that that approach was rejected by five Justices in *Lohr*; they determined that a significant number of common law tort actions were preempted by § 360k(a), notwithstanding that all such actions are premised on broadly applicable tort principles. Moreover, nothing in the statute supports Petitioner's constricted definition of a state "requirement." Section 360k(a) refers to preemption of "any" applicable requirement. Moreover, even when a tort judgment is based on generally applicable common law rules, it has the effect of imposing on the defendant a product-specific common law duty that does not leave it free to continue marketing its product in the same way as it has in the past. As *Bates* explained, where (as here) any judgment would be premised on common law rules that would dictate future marketing decisions, such rules are "requirements" within the meaning of federal preemption statutes. *Id.* at 446.

### C. States Undermine the Objectives of the MDA When They Second-Guess an FDA Decision to Approve Marketing of Life-Saving Medical Devices Pursuant to FDA-Mandated Design and Labeling Requirements

Petitioner asserts that the Second Circuit's preemption rule will foreclose remedies for many people injured by defective PMA devices. Pet. Br. 43-46. That assertion is without merit.

When it approves a PMA application for a medical device, FDA thereby determines that a medical device designed, manufactured, and labeled in accordance with the FDA-mandated specifications *is not defective*. Thus, by limiting a patient's litigation options, all § 360k(a) is doing is preventing the patient from suing the manufacturer of a non-defective device. FDA continues to monitor medical devices after it has approved a PMA application and marketing of the devices has begun. If it subsequently determines that a device is defective, it has the authority *inter alia* to withdraw approval, 21 U.S.C. § 360e(e), and to recall devices already in the marketplace. 21 U.S.C. § 360h(e). But until such time as FDA takes action to reverse a decision approving the marketing of a device with FDA-mandated design specifications and labeling, § 360k(a) prohibits States from arriving at a contrary decision by applying a different set of requirements to the device.

Moreover, § 360k(a) does not leave injured patients without remedies. For example, as the Second Circuit held, they are still free to pursue other remedies against the manufacturer, including negligent manufacture and breach of express warranty. Alternatively, they can pursue remedies against others who may be responsible for the injuries, such as their physicians. But Congress recognized that no medical

product is without risk and that use of Class III medical devices often results in injuries for which no one can be deemed blameworthy. Under those circumstances, Congress acted reasonably in limiting the liability of manufacturers who, like Medtronic in this case, have marketed their medical devices in conformance with all applicable FDA requirements and after FDA has determined that their devices are safe and effective.

The MDA was intended to strike a balance between the need to protect the public from unsafe and ineffective medical devices and the danger that unnecessary restrictions would deter innovations in medical device technology. *See* H.R. Rep. No. 853, 94th Cong., 2d Sess. 9 (1976), *reprinted in* Daniel F. O'Keefe, Jr. & Robert A. Spiegel, *An Analytical Legislative History of the Medical Device Amendments of 1976*, App. III (1976). Section 360k(a) addresses the latter concern by ensuring that excessive tort liability does not deter medical innovation. It also addresses Congress's concern that, "if a substantial number of differing requirements applicable to a medical device are imposed by jurisdictions other than the Federal government, interstate commerce would be unduly burdened." *Id.* at 45. *See also* Pet. App. at 33a-34a ("It is certainly conceivable that different juries would reach conflicting verdicts about the same medical devices, thus rendering it almost impossible for a device to comply simultaneously with its federal PMA (which, after all, can only change after an extensive process) and with the various verdicts issued by different juries around the country.").

## II. PETITIONERS' DESIGN DEFECT AND FAILURE-TO-WARN CLAIMS ARE IMPLIEDLY PREEMPTED BY THE MDA

The issue before the Court is whether Congress intended to preempt common law actions of the sort being pressed by

Petitioner. The Second Circuit relied on the express preemption provisions of § 360k(a) to answer that question in the affirmative. WLF agrees with the appeals court's analysis. In addition, WLF submits that the answer would be the same if this Court were to employ an implied preemption analysis. Accordingly, the appeals court decision can be sustained on either basis.

### A. Implied Preemption Is Fairly Encompassed Within the Question Presented

The Court granted review to consider whether, as found by the Second Circuit, Congress intended to preempt common law design defect and failure-to-warn claims filed against the manufacturer of a PMA medical device. Accordingly, implied preemption is fairly encompassed within that question; the ultimate issue (congressional intent) is the same whether it is determined on the basis of express statutory language or is inferred on the basis of the structure of the MDA.[7] Once review is granted to consider an issue, the Court has never limited the parties to the specific arguments on that issue that were raised or considered below. *See Lebron v. Nat'l Railroad Passenger Corp.*, 513 U.S. 374, 379 (1995) ("Our traditional rule is that 'once a federal claim is properly presented, a party can make any argument in support of that claim; parties are not limited to the precise arguments they raised below.'") (quoting *Yee v. Escondido*, 503 U.S. 519, 534 (1992).

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[7] *See Lohr*, 518 U.S. at 485 ("'[T]he purpose of Congress is the ultimate touchstone' in every preemption case.") (quoting *Cipollone*, 505 U.S. at 516).

### B. The Court Has Regularly Inferred Congressional Intent to Preempt State Laws That Conflict with Federal Law

When express statutory language does not directly answer whether and to what extent Congress intended to preempt state law, "courts must consider whether the federal statute's 'structure and purpose,' or nonspecific statutory language, nonetheless reveal a clear, but implicit, preemptive intent." *Barnett Bank of Marion County, N.A. v. Nelson*, 517 U.S. 25, 30 (1996) (quoting *Jones v. Rath Packing Co.*, 430 U.S. 519, 525 (1977)). Findings of such "clear, but implicit, preemptive intent" have generally been grouped into two categories: (1) field preemption; and (2) conflict preemption. *Freightliner Corp. v. Myrick*, 514 U.S. 280, 287 (1995).

Field preemption is said to occur:

> [I]f a scheme of federal regulation is "so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it," if "the Act of Congress . . . touch[es] a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject," or if the goals "sought to be obtained" and the "obligations imposed" reveal a purpose to preclude state authority. *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947).

*Wisconsin Public Intervenor v. Mortier*, 501 U.S. 597, 605 (1991).

Conflict preemption is said to occur:

> [T]o the extent that state and federal law actually conflict. Such a conflict arises when "compliance with

> both federal and state regulation is a physical impossibility," *Florida Lime and Avocado Growers, Inc. v. Paul,* 373 U.S. 132, 142-143 (1963), or when a state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Hines v. Davidowitz,* 312 U.S. 52 (1941).

*Wisconsin Public Intervenor,* 501 U.S. at 605.

### C. Recovery Under the Riegels' Causes of Action Is Preempted Because It Would Undermine the PMA Process Established by Congress

WLF submits that the Riegels' causes of action are impliedly preempted because they stand as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. Recovery under those causes of action would undermine the PMA process established by Congress, by second-guessing FDA determinations that approved products are not defective when marketed in accordance with the FDA-approved labeling and design specifications.

In *Buckman*, the Court held that federal law preempted state-law claims that a medical device manufacturer made fraudulent misrepresentations to FDA for the purpose of obtaining FDA approval for its device. *Buckman*, 531 U.S. at 348. The Court unanimously held that Congress had impliedly intended to preempt such fraud-on-the-FDA claims when it adopted the MDA and the FDCA, because adjudication of such claims would conflict with the FDA product-approval process. *Id.* The Court explained:

> The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Agency, and that this authority is used by the agency to achieve a somewhat delicate balance of

> statutory objectives. The balance sought by the Agency can be skewed by allowing fraud-on-the-FDA claims under state tort law.

*Id.*

Similarly, permitting the Riegels and other injured plaintiffs to bring state-law suits alleging that a PMA medical device is defectively designed or improperly labeled would undermine FDA requirements mandating that the device be designed and labeled in that precise manner. If state officials have reason to believe that PMA medical devices being marketed within their jurisdiction are defective, they can go to FDA to report their concerns and urge FDA to exercise its power to prevent further marketing of the drug. But allowing States to go forward independently with proceedings designed to determine whether the FDA-mandated product design is defective is an invitation to chaos.

Indeed, it was precisely such concerns about conflict between federal and state regulatory requirements that underlay the Second Circuit's express preemption finding. The appeals court explained its concern as follows:

> Yet the Riegels' claims would premise liability on Medtronic's failure to have done something with the Evergreen Balloon Cath[et]er other than adhere to the PMA-approved standards. [¶ ] In fact, it is unclear what a manufacturer of a PMA-approved device would do when faced with a jury verdict on a plaintiff's common law claims, given that the manufacturer would nonetheless be unable to make any modifications affecting the device's safety and effectiveness without obtaining further FDA approval. Moreover, it is certainly conceivable that different juries would reach conflicting verdicts about the same medical devices, thus

> rendering it almost impossible for a device to comply simultaneously with its federal PMA (which, after all, can only change after an extensive process) and with the various verdicts issued by different juries around the country.

Pet. App. 33a-34a. Such concerns could equally well have been cited as the basis for a conflict preemption determination.

Of course, Congress is free to disclaim an interest in preempting state law, even state law that (as here) conflicts with a federal regulatory regime by standing as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress. But Petitioner has pointed to nothing in the MDA suggesting such a congressional intent. This Court has held that, in the absence of affirmative statutory evidence that Congress did not want to preempt conflicting state law, normal conflict preemption principles are applicable. *Geier v. American Honda Motor Co.*, 529 U.S. 861, 873-74 (2000) ("no airbag" tort suits against auto manufacturers held impliedly preempted by federal auto safety rules, in absence of evidence that express preemption clause and savings clause in National Traffic and Motor Safety Act of 1966, 15 U.S.C. § 1381 *et seq.*, were intended to supplant conflict preemption analysis).

Riegels' causes of action cannot be defended based on an argument that federal design and labeling requirements serve merely as a floor and that states are permitted to impose more exacting safety requirements. FDA specifies precise design specifications for a medical device based on a detailed assessment that the prescribed design is safe and effective. *See, e.g.* 21 C.F.R. §§ 814.20, 814.44, 814.80. Congress cannot have intended to permit a state-court jury to second-guess such design decisions, where the practical effect would

be to require a manufacturer to adopt a different design – one that FDA might well decide is neither safe nor effective.

Similarly, FDA imposes labeling requirements based on its considered determination regarding the proper mix of contraindications and warnings. FDA regularly directs manufacturers to limit the strength of warnings included on a label, to avoid scaring away consumers who would benefit from using the product. Yet, if Petitioner were to prevail on her failure-to-warn claim, New York would in effect be requiring Medtronic to alter the labeling mandated by FDA. Under such circumstances, Congress is deemed to have impliedly preempted such common law suits.

Indeed, based on concerns that overwarning on product labels (brought about in reaction to common law failure-to-warn suits) could cause adverse health effects, FDA has adopted the position that failure-to-warn claims against drug manufacturers are impliedly preempted in a broad range of circumstances. FDA, *Requirements on Content and Format of Labeling for Human Prescription Drug and Biological Products*, 71 Fed. Reg. 3922, 3935 (Jan. 24, 2006) ("Overwarning, just like underwarning, can . . . have a negative effect on patient safety and public health.").

Perhaps the most well-known recent example of overwarning involves depression drugs. Beginning in 2004, FDA began focusing on reports that adolescent patients taking drugs in the selective serotonin reuptake inhibitor (SSRI) class were having suicidal thoughts shortly after beginning drug therapy. After consulting with advisory committees regarding the appropriate risk management strategy in response to these reports, FDA decided to seek labeling revisions for all SSRIs. On March 22, 2004, FDA issued a Public Health Advisory recommending that labeling be modified to reflect potential suicide risks. FDA noted in the Advisory that it had "not

concluded that [SSRI side effects] are a precursor to either worsening of depression or the emergence of suicidal impulses," but it still recommended the change to alleviate "concern." Public Health Advisory, FDA, Worsening Depression and Suicidality in Patients Being Treated With Antidepressant (Mar. 22, 2004), *available at* http://www.fda.gov/cder/drug/antidepressants/AntidepressanstPHA.htm.

Shortly after the labeling change, the psychiatric community, patients, and caregivers began expressing concern about undertreatment of depression and a sudden spike in suicidal behavior. Pediatric antidepressant prescriptions had fallen by about 50 percent between 2003 and 2005, according to a study published in June 2007 in *The American Journal of Psychiatry*. Anne M. Libby, Ph.D. et al., *Decline in Treatment of Pediatric Depression After FDA Advisory on Risk of Suicidality With SSRIs*, 164 Am. J. Psychiatry 884, 887 (2007). A September 2007 study in that journal reported that, as pediatric antidepressant prescriptions fell in 2003-2004, the adolescent suicide rate rose by 14 percent.[8] The authors of the study reasoned that "the public health warnings may have left some of the most vulnerable youths untreated." Robert D. Gibbons, Ph.D. et al., *Early Evidence on the Effects of Regulators' Suicidality Warnings on SSRI Prescriptions and Suicide in Children and Adolescents*, 164 Am. J. Psychiatry 1356, 1358-1359 (2007).

The same concerns regarding overwarning apply to medical devices. If, in response to common law failure-to-warn suits, device manufacturers are required to add warnings

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[8] Data available from the Centers for Disease Control and Prevention on U.S. suicide rates was only available at the time of the study through 2004.

to their product labels – warnings that are in excess of those deemed appropriate by FDA – one can expect a certain number of patients to abstain inappropriately from use of medically indicated device. Congress did not intend to permit state juries to second-guess FDA's considered judgment regarding which warnings should be placed on the label of a medical device.

### D. The Existence of an Express Preemption Provision in the MDA Does Not Preclude an Implied Preemption Finding

The fact that the MDA includes an express preemption provision does not preclude a finding of implied preemption. The Court has on several occasions held that a common law cause of action is impliedly preempted by federal law even though the federal statute at issue contained an express preemption provision. For example, in *Geier*, the Court held that "no airbag" common law suits are implied preempted by federal highway safety law, after finding that the express preemption provision of the National Traffic and Motor Safety Act of 1966 did *not* preempt such suits. *Geier*, 529 U.S. at 869 (existence of express preemption provision "does not foreclose (through negative implication) any possibility of implied conflict preemption). In *Buckman*, the Court determined that fraud-on-the-FDA lawsuits are impliedly preempted (under conflict preemption analysis) by the MDA and the FDCA and thus deemed it unnecessary to determine whether § 360k(a) also preempted such lawsuits. *Buckman*, 531 U.S. at 348 n.2.

Indeed, the *Lohr* plurality, while generally looking askance at express preemption (under § 360k(a)) of common law suits against manufacturers of § 510(k) medical devices, explicitly held open the possibility of implied conflict preemption in a proper suit. *Lohr*, 518 U.S. at 503 (plurality opinion). Moreover, Justice Breyer's concurring opinion, while nominally focusing on whether § 360k(a) preempts

common law causes of actions against device manufacturers, makes clear his view that the strongest arguments supporting preemption are ones demonstrating that a state common law rule is interfering with FDA regulation of medical devices. *Lohr,* 518 U.S.. at 503-508 (Breyer, J., concurring in part and concurring in the judgment).

## CONCLUSION

The Washington Legal Foundation respectfully requests that the Court affirm the judgment of the appeals court.

Respectfully submitted,

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